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Preface

The control of micronutrient malnutrition, notably vitamin A deficiency, iodine-deficiency disorders, and iron-deficiency anaemia, presently occupies the attention of nutrition and public health workers throughout the developing world. In Asia, particularly, micronutrient deficiencies have been recognized as significant causes of morbidity and mortality among vulnerable population groups. Thus, the search for effective strategies for the control of these deficiencies has been intensified in recent years.

Fortification of foods that are commonly consumed by the population at risk has been demonstrated to be a viable and cost-effective food-based strategy for the control of micronutrient deficiencies. However, although food fortification has been practised for many years in some countries in the Asian region, notably the more affluent ones, national food-fortification programmes have yet to be fully implemented in areas where this problem abounds. Barriers remain to their widespread implementation. These can be attributed to a lack of information within industry, government, and the general public as well as a lack of open communication among these sectors. It would, therefore, be highly desirable to bring together representatives of these sectors in a multisectoral forum to discuss the many issues related to food fortification that concern them, namely, scientific and technological aspects, transfer of technology, initiation and implementation of food-fortification programmes, advocacy and information campaign strategies, and systems of quality assurance and monitoring. Discussion of appropriate legislation, guidelines, and regulations is also needed to remove unresolved questions from the industry and consumers. Further research needs to seek out and identify more effective methods and strategies.

On 3–5 December 1996, the International Life Sciences Institute (ILSI) South-East Asia convened a re-

gional conference in Manila, Philippines, on “Food Fortification: Science, Technology, and Policy,” to discuss the many issues related to fortification. With the collaboration of the Food and Nutrition Research Institute (Department of Science and Technology), the Nutrition Centre of the Philippines, and the Nutrition Service (Department of Health), the conference was attended by some 230 participants from South-East Asia and other parts of the world.

During the conference, leading international and regional speakers presented the many issues relating to technology, safety, legislation, economic perspectives, and the need to forge partnerships among industry, government, and academics. Case studies were presented on the fortification of sugar, wheat flour, and margarine with vitamin A; salt with iodine; rice and complementary foods with iron; and beverages and instant noodles with multiple nutrients. Panel discussions followed, focusing on strategies of getting started on food fortification, educational advocacy, policy and legislation, and monitoring and evaluation. The conference resulted in the Manila Declaration on Food Fortification, embodying the recognition by the participants of the urgency of eliminating micronutrient malnutrition and of the benefits and viability of food fortification for its control.

The papers that follow were presented at the conference. They are being published with the hope that leaders in government, industry, academics, and consumer groups who are concerned with the improvement of diets through fortification will benefit from the insights and experiences brought out during the conference.

Rodolfo Florentino
President, Philippine Association of Nutrition

Overview: Rationale and elements of a successful food-fortification programme

Ian Darnton-Hill

Abstract

Over 2,000 million people, or more than one of three individuals throughout the world, are at risk for iron, vitamin A, or iodine deficiency. The three main approaches to addressing micronutrient deficiencies are fortification, supplementation, and dietary diversification. Although fortification of staple foods has played a significant role in the nutritional well-being and health of the more industrialized nations, it has not been considered an option for less developed countries because of the lack of centrally processed foods and poorly developed food-marketing systems. As food markets expand, however, fortification options are becoming increasingly available. This paper identifies past and present successes and failures, as well as the facilitating factors and constraints that need to be addressed. Based on recent experience and the lessons learned, successful programmes require at least the following: political will and support and the willingness to legislate or regulate; private-sector involvement; public-sector support; willingness of both sectors to enforce quality assurance programmes; good data on consumption patterns; social acceptability of fortified food, implying no change in organoleptic properties; and minimal change in cost.

Introduction

The elimination of vitamin A deficiency and iodine-deficiency disorders and the substantial reduction of iron-deficiency anaemia have been endorsed as achievable goals by more than 159 countries [1]. This paper will look at one of the main strategies being used to address this problem: fortification and the elements of

a successful programme. Other complementary approaches to prevent and control micronutrient malnutrition include diet diversification, pharmacological supplementation, and public health measures, such as immunization and control of infectious diseases.

Extent of the micronutrient problem

Micronutrient malnutrition is a serious threat to the health and productivity of more than 2,000 million people worldwide, even though it is largely preventable [2]. Because of their high prevalence and close association with childhood illness and mortality, the three micronutrient deficiencies of greatest public health significance are those of iron, vitamin A, and iodine. Women and children are more vulnerable to micronutrient deficiencies because of their added requirements for reproduction and growth, respectively [3].

Fortification as a prevention and control approach

Fortification is defined by the Codex Alimentarius as “the addition of one or more essential nutrients to a food, whether or not it is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups” [4].

Micronutrient interventions, and particularly fortification, have been identified by the World Bank as among the most cost-effective of all health interventions [5]. There is a wealth of experience in fortifying foods, and it has been a major factor in the control of micronutrient deficiencies in the industrialized world [6]. It is now being extended in some of the wealthier nations to provide preventive action against deficiencies of nutrients that are not in real shortage in the diets of the general population. For example, in Australia thiamine is added to wheat flour to address the relatively high levels of cerebral degeneration (which

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Mention of the names of firms and commercial products does not imply endorsement by the United Nations University.

are seen, however, in less than 1% of the population) associated with diets low in thiamine and high in alcohol (Wernicke-Korsakoff syndrome) [7]. In the United States flour is fortified with folate to prevent congenital malformations of the spinal cord (neural tube defects, including spina bifida), which affect approximately 2 in every 1,000 pregnancies [8].

Until recently it was presumed that fortification was not a suitable intervention in the less industrialized countries, since previous experience in developing countries has not always been encouraging [9]. However, there are now enough successful examples to suggest this is no longer true. Mora and Dary^{*} list 17 countries in Latin America that now fortify foods with at least one micronutrient and sometimes more.

Requirements for effective fortification in food-aid programmes will not be discussed, although the issue is very important and is currently receiving a lot of attention. For the purposes of this review, it suffices to mention that fortification of food aid for displaced persons and refugees was endorsed at the International Conference on Nutrition (ICN), which included the recommendation that “donor countries and involved organizations must... ensure that the nutrient content of food used in emergency food aid meets the nutritional requirements if necessary through fortification, or ultimately supplementation” [1].

Fortification programmes

Some experiences with fortification, especially in developing countries, will be examined below.

Vitamin A

Fortification has been important in reducing deficiencies of vitamin A, especially in Latin America where sugar is fortified with it. Other fortification vehicles have included whole wheat, monosodium glutamate and instant noodles, rice and other cereals, tea, fats and oils, milk and milk powder, rice, salt, soya bean oil, and infant formulas [10].

Sugar

The fortification of sugar with vitamin A is actually a success story but does offer a couple of lessons. Despite demonstrated success in the Guatemalan programme in the early 1970s, with increases in the status of recipients' vitamin A levels and, indirectly, haemoglobin levels, the programme faltered in the 1980s [11]. This

was because of a lack of continuing government commitment, indifference from the producing sector, economic limitations, and, presumably, a lack of self-sustainability (in terms of passing on costs, etc.), so that it could not continue without some public-sector involvement. It has now been revitalized, although some technical improvements are still needed. In a start-up programme in Bolivia, involving a partnership among government, donors (US Agency for International Development and UNICEF), and a commercial firm, sustainability has yet to be assured, although there are currently plans for scaling up nationally by the private sector. However, this is happening for reasons of economic scale and before all the technological problems have been clearly resolved. For instance, a recent evaluation of the levels of vitamin A in fortified sugar has shown them to be quite low. Ecuador had moved along the path towards fortification, but after a meeting on sugar fortification in Guatemala early in 1996, the government decided that the technical problems were still too unresolved for the country to commit to such a programme. Nevertheless, sugar has been fortified with vitamin A in Costa Rica, El Salvador, Guatemala, Honduras, and Panama. Other countries, such as the Philippines in Asia and Uganda in Africa, are also interested.

Wheat

An interesting programme using whole wheat was developed in Bangladesh with technical assistance and support from the US Agency for International Development through Helen Keller International. Because wheat is the less preferred staple, the fortification programme would have been automatically targeted to the poor. It became, however, an example of a technically feasible, properly developed programme that failed politically because it did not adequately involve the policy makers and those most affected [9, 12]. The Philippines is currently testing vitamin A fortification of wheat flour.

Monosodium glutamate

The project to fortify monosodium glutamate (MSG) with vitamin A was also technically feasible and had been properly developed by consumption, taste, and impact trials in both Indonesia and the Philippines [13, 14]. There are several reasons why it failed at the time. Some of the technological developments were released too early and subsequently found not to have been resolved, e.g., yellowing of the MSG in a product that sold itself as “pure white” [9]. Key government policy makers were not convinced of the safety of MSG, despite statements by the Food and Agriculture Organization/World Health Organization (FAO/WHO) regarding its safety, and there was a further lack of conviction on the part of the private sector in the programme's cost-effectiveness. It is possible that it may still go ahead in Indonesia as a purely private-sector initiative. How-

^{*}Mora JO, Dary O. Strategies for prevention of micronutrient deficiency through food fortification. Lessons learned from Latin America. Presented at the 9th World Congress of Food Science and Technology, Budapest, Hungary, 1995.

ever, in the Philippines the programme seems permanently stalled, and other vehicles are now being investigated.

Rice and other cereals

Again, although technically feasible as a pilot, the fortification of rice with vitamin A has not proceeded to the national level in any country. Both the Dominican Republic and the Philippines have attempted to fortify rice with vitamin A [6]. In the Philippines the 15% to 20% losses from water washing were considered unacceptable [9]. A feasibility trial of a fortified rice premix is under way in Indonesia, but the government has made known its lack of enthusiasm for fortifying the national staple. In Brazil the programme is still at the stage of testing bioavailability [10]. In Venezuela, on the other hand, pre-cooked corn flour, which is used to make *arepas*, a staple food in the national diet, has been successfully fortified with vitamin A, thiamine, riboflavin, niacin, and iron [15].

Tea

In three countries, India, Pakistan, and Tanzania, technically feasible programmes to fortify tea with vitamin A have not proceeded, although they have been properly developed and tracked [10].

Fats and oils

In developed countries, fats and oils have been the main vehicles of vitamin A fortification, often with other micronutrients such as vitamin D. The production of a variety of vegetable oils is high throughout the world, and consumption is increasing, especially among the low socio-economic sectors of the population. Thus, oil represents an ideal fortification vehicle to reach these groups [10]. An important example of cooperation among the food industry, government, and academics has been the relatively successful fortification of Star Margarine with vitamin A in the Philippines, which has led to the fortification of canned sardines. Programmes of fortifying margarine with vitamin A are currently ongoing in Brazil, Chile, Colombia, El Salvador, Mexico, and other countries around the world, especially developed countries. In India, red palm oil is added to other edible oils, and vitamin A-fortified soya bean oil is being tested in Brazil [16].

Summary of vitamin A—fortification programmes

Success in vitamin A fortification has depended on sustained political commitment (both in-country and by donors), persistence with technical development of fortificant technologies to overcome problems, increased awareness of the health consequences of vitamin A deficiency by governments, and involvement of the private sector. Fortification programmes have been shown to be effective in a variety of settings [11, 15, 17].

Iron

Compared with other strategies used for correcting iron-deficiency anaemia, with which relatively little progress has been made worldwide, iron fortification is the cheapest to initiate and maintain, reaches the largest number of people, guarantees sustainability [18], and lacks the side effects and logistical problems that have often affected iron-supplementation programmes. Long implemented in developed countries, iron fortification is now being adopted in several Latin American and Caribbean countries in accordance with government regulations. In developed countries, wheat flour and cereal-based foods have had significant success as vehicles for iron. Other vehicles include infant weaning foods, salt, sugar, rice, curry powder, fish sauce, soy sauce, bakery products, beverages, biscuits and cookies, low-fat milk, chocolate milk, maize flour, margarine, and water [4, 10].

Rice

There has been extensive commitment to fortify rice with iron by the Filipino government, which, unlike the Indonesian government, recognizes the good sense in fortifying the national staple. However, technical problems with discolouration, the multitude of rice-milling factories, and a lack of demonstrated success in a pilot trial promoting the idea of buying sachets of fortified rice grains to add to unfortified rice (which people picked out after the rice was washed) indicate that this programme has not proceeded as expected, despite government support. Iron-fortified rice may have a role in government-subsidized rice stabilization programmes, but in this case, the programme's sustainability would become more problematic.

Other cereals

Programmes to fortify other cereals with iron have generally been successful, although, given the inhibitory effect of cereals on iron bioavailability, cereal fortification may not be the most efficient way to reduce iron-deficiency anaemia [10]. However, it has been useful in many countries and has been found to be cost-effective [6, 10]. Chile has used animal blood as a convenient and cheap source of iron for fortification programmes [10]. Venezuela has fortified pre-cooked corn flour, to which other micronutrients, including vitamin A, have been added. Wheat flour (without vitamin A) has also been fortified with iron successfully on a national basis [15]. The OMNI Project is currently working with the Sri Lankan government to test the efficacy of the fortification of wheat flour with iron for tea plantation workers, with the intention of scaling up to a larger programme when its efficacy has been established. The private sector in Indonesia and other Asian countries is developing instant noodles fortified with iron and other nutrients, aiming initially at a middle-income more than a low-income market.

Salt and other products

Fortification of salt with iron has been implemented on a limited scale in India and Thailand, but although it appears to be technically feasible, it has not, at this time, been adopted more widely [10]. Iron-fortified salt may have a greater role in double fortification (see below). Other vehicles of fortification include rice flour (Argentina and Chile), fish sauce (Thailand), curry powder (South Africa), and such products as barley sprout flour, coffee, grain amaranth cereal, maize meal, potato starch, and wheat flour noodles, all of which are currently being investigated and developed; however, their future on a large and sustainable scale remains uncertain [10]. In Brazil there is an experimental project in some day-care centres to fortify water-filtration systems with iron.

Summary of iron-fortification programmes

Success with iron fortification has involved finding appropriate iron fortificants and food vehicles in terms of organoleptic properties, getting government commitment (often by legislation as a political act), and increasing awareness of the extent of the problem of iron deficiency as well as the fact that other interventions have not been particularly sustainable or successful. Fortification with iron has also been shown to be effective, e.g., in Chile and Venezuela [15, 19].

Iodine

Iodine has been most vigorously pursued as a fortificant of salt for a variety of reasons, especially those factors which lead to or contribute to successful programmes: consumption in fairly consistent amounts by all sectors of society, consumption at roughly consistent levels throughout the year, and technological feasibility and cost-effectiveness. It has also had the advantage of strong international and government commitment and an international experience that has been freely shared. Countries with effective iodized salt programmes have shown sustained reductions in the prevalence of iodine-deficiency disorders [6, 10, 20]. However, sustainability has not always been ensured, and the populations of countries like China, Germany, and Switzerland showed increases in the prevalence of iodine deficiency where commitment to the programme was not maintained.

Another problem has been the assumption that fortification could be imposed from the top without the involvement or commitment of consumers and, sometimes, policy makers. This has led, in some cases, to consumer groups suing governments for the right to consume non-iodized salt, e.g., in India, and to both consumers and government not being aware of the importance and significance of iodization in terms of national health and economic productivity. It is essential that people know why their salt is iodized and what the associated benefits are, so that the programme ensures

sustainability through consumer demand. It has also been shown that all salt (including salt intended for animals and industry) must be iodized to ensure the success and sustainability of these programmes [10, 20].

Other vehicles of iodization have included bread, sweets, milk, flour, sugar, and condiments. Fortification of animal feeds can be useful in increasing the iodine content of animal products [4]. Dietary intake of iodine can be increased by adding iodine to drinking water (as in schools in Thailand) or to the local water supply (as in China), or by using a commercial attachment to water pumps with slow-release resins, which is currently under trial.

In summary, the success with iodization has been due to its relative technological straightforwardness, much international experience, proven efficacy, and enormous support and advocacy from the international donor community, such as UNICEF and the International Council for the Control of Iodine-Deficiency Disorders (ICCIDD) [20].

Multiple fortification

Multiple fortification of foods is a possible way of addressing deficiencies of two or more micronutrients at the same time in a cost-effective manner, although some organizational, technical, and micronutrient-interaction constraints need to be addressed in developing countries. Nevertheless, progress is being made, e.g., in double fortification of salt with iodine and iron [21]. Multiple fortification has been successful in the more developed countries, particularly in fortification of cereals and infant-weaning foods [10]. In some cases, fortification with two micronutrients (e.g., iron and vitamin A or iron and vitamin C) would enhance the effects of fortification on micronutrient status [6, 22].

Nevertheless, it is important to remember that although scientific and engineering advances have resulted in an increasing number of options regarding the choice of fortificant compound and processing procedures, there is a limit to the possibilities of new technologies. For example, multiple fortification of certain food vehicles may result in substantially increased cost and reduced bioavailability [23]. Changes in the sensory or organoleptic characteristics of the food can also be a problem. For example, encapsulation of micronutrients may not be cost-effective in some countries, even though the technology is theoretically available.

Other micronutrients

The focus of the international community has been on the three most prevalent micronutrient deficiencies (vitamin A, iron, and iodine). Clearly, other micronutrients, such as vitamins D, E, and C and the B-complex vitamins, are also likely to be important in many settings and are used as fortificants in many coun-

tries in different combinations. There is mounting evidence that zinc deficiency may be important in many population groups. However, for focus, and reflecting current international priorities, this paper has only addressed vitamin A, iron, and iodine.

Constraints to successful programmes

Factors involved in constraining the development of successful programmes might be categorized as technical, socio-economic, infrastructural, and political.

Technical constraints

Technical problems must be considered, such as the installation and maintenance of new machinery, the stability of added micronutrient fortificants in the food, and, sometimes, the need to develop new technologies, such as adding vitamin A to MSG. Innovative fortificant development does not appear to have been a major constraint; for example, wheat grains have been coated with a clear, vitamin A-containing shellac. However, some have yet to be fully overcome, such as double fortification of salt with iron and iodine. Technical constraints to successful fortification programmes include the purity of salt needed for effective iodization, the presence of phytates and other substances that affect the bioavailability of non-haem iron fortificants, and the storage conditions necessary for vitamin A-fortified foods [4, 6, 10]. The long time periods and high costs required for the development of new combinations of fortificants and vehicles must be considered when planning fortification activities [9].

Socio-economic constraints

Socio-economic constraints include the facts that fortification relies on a centrally processed and marketed food vehicle and that only those purchasing and consuming the food, who may not be the very poor, will benefit [6, 24]. Also, such foods may not be available or accessible in less developed countries, particularly to the more at-risk, poorer rural segments of society. The transfer of the costs of fortification to the consumer, even when slight, can deter the very poor from purchasing such foods. Setup costs can also be an inhibiting factor at the start of a fortification programme. The demand that programmes make on foreign exchange may represent another constraint, unless it is feasible to manufacture the fortificant or the fortified foods at the local or regional level [6].

Infrastructural constraints

Experience of the public and private sectors working together is often limited, although such cooperation is

essential. Cooperation of the food industry has often not been ensured at an early enough stage in programme development. Linkages between the health care system and the private food sector are usually weak. A background paper for a recent FAO consultation concluded that active government participation must continue for food-fortification programmes to succeed in developing countries [25]. Other infrastructural constraints in a country may affect quality assurance and regulation, suggesting that the lack of adequate food-control systems could constrain the success of food-fortification programmes. Distribution can be affected by poor roads, inadequate storage and delivery systems, etc., particularly in rural areas. This lack of infrastructure has meant that the time lag between starting a programme to re-tailing fortified food has tended to be longer than anticipated. Lack of adequate political, financial, and technical support for an efficient monitoring and surveillance system is often a cause of programme failure as well [4].

Political constraints

Political support may be lacking for a number of reasons. Nutrition and health are relatively low priorities in national budgets when there are many competing demands. Furthermore, the lack of good programme evaluations in the past has failed to provide a convincing body of data for policy makers [6], although this is changing. There is often a concern about start-up costs and the costs of regulation. A simple lack of awareness of the magnitude of micronutrient malnutrition and its economic and health costs is frequently an underlying constraint. Political and financial incentives can be offered in the form of tax exemptions; import licences and loans for equipment and raw materials; initial subsidies to procure fortificants; assistance in developing an in-process quality control system; training of production, administrative, and marketing personnel; training of the wholesale and retail sector; and prohibition of illegal imports. However, these incentives are rarely offered. Mandatory quality assurance and control can be ensured through legislation and regulations [10], but industry still needs to comply. Care needs to be taken that special provisions given to one firm do not distort incentives for other companies, as happened in the Philippines, when one company was given the concession of an extended monopoly that effectively inhibited competitors from fortifying salt.

Other constraints

A major overall constraint on fortification is the lack of an obvious food vehicle that can reach the targeted recipients. In many cases, identification of suitable vehicles is made difficult by the absence of reliable information on the dietary habits of the target population [4]. The major problems involved in fortifying foods

include the identification of suitable vehicles, selection of appropriate fortificant compounds, determination of technologies to be used in the fortification process, and the implementation of appropriate monitoring mechanisms to determine whether the goals of the programme are being met [4].

Facilitating factors in successful programmes

Technical facilitating factors

There is a minimum set of requirements that a fortified food must have to be successful (table 1). Innovations in appropriate technology, especially in small-scale salt iodization, village-level mixers in Thailand, and small mechanized and relatively cheap machines manufactured in Bangladesh, China, and India, have proven important facilitating factors. Newly emerging markets in less industrialized countries are encouraging the development of more stable fortificants and the fortification by the private-sector food industry of their own commercially sold foods, e.g., margarine in the Philippines. Consumer acceptance through the testing of fortified food, which must be done at several locations and under varying cooking conditions in the country in which fortification will take place, must also be ensured. Where consideration has been given to problems potentiated by increasing production activities from the pilot level to industrial scale, success has been more likely.

Socio-economic facilitating factors

Fortification is largely socially acceptable and does not require active consumer participation or changes in cooking or eating habits if organoleptic properties are maintained. When the different sectors of society participate actively as partners, successful programmes are more likely to result. These should include relevant government institutions, the food industry, trade organi-

zations, consumer organizations, academic and research facilities, marketing specialists, and interested international organizations and agencies [9, 26]. For example, the overall responsibility for quality control inside the country often rests with the Public Health Department, but consumer organizations can and should be involved. Schools and industry are both involved in the monitoring of salt-iodization programmes in Ecuador [27], a relationship that has recently been proposed in Eritrea. In India non-governmental organizations in Uttar Pradesh are involved in monitoring salt for iodization at the retail and household levels, and local politicians are involved to the extent that they point out inadequacies to the provincial and national parliaments [10].

Infrastructural facilitating factors

A major infrastructural advantage is the existence of a commercially processed food with a widespread distribution system, thus making the introduction of the micronutrient-fortified food relatively easy. Effective fortification needs to be supported by suitable legislation and regulations; however, legislative measures are more likely to allow for successful programmes when they do not make fortification practices cumbersome or restrict communication about the availability of the fortified food. This has been avoided by including extensive consultation with the scientific community, industry, consumers, and other relevant interested parties in the legislative process [4]. When good quality assurance and quality control exist, particularly as a partnership between government and industry (e.g., in the development of the Sangkap Pinoy quality seal in the Philippines), proper fortification of some commercial foods through successful programmes is ensured.

Political facilitating factors

Increased awareness of the health, developmental, and economic consequences of micronutrient malnutrition is important, especially for sustainability. Political advocacy of fortification is sometimes more direct in developing countries, as exemplified by the endorsement of programmes to prevent micronutrient malnutrition at the highest levels in the Philippines, Thailand, and some other countries. The relative cost-effectiveness of fortification is a strong incentive for governments if they can be convinced. Finally, fortification has high sustainability [6, 11].

TABLE 1. Requirements for a fortified food

<ul style="list-style-type: none"> » Commonly consumed by the target population » Constant consumption pattern with a low risk of excess consumption » Good stability during storage » Relatively low in cost » Centrally processed with minimal stratification of the fortificant » No interactions between the fortificant and the carrier food » Contained in most meals. with the availability unrelated to socio-economic status » Linked to energy intake

Source: ref. 4.

Conclusions

The concepts of what constitutes a successful programme and what fortification with micronutrients attempts to achieve have undergone something of a paradigm shift over the last few years. Previously

the intention was to target those most at risk by programmes in the public sector with donor support. In government-subsidized programmes, sometimes with a political agenda, equity aim, or intentions for very specified groups such as refugees, this is still appropriate. However, there is now a strategy to move the targeted population to the left of a distribution curve (fig. 1) so that a larger portion of society will be addressed by the private sector. Where these foods are not able to reach or be bought by the poorest or those generally most at risk, these more vulnerable populations may need to be addressed by other initiatives, such as targeting with supplements or with feeding programmes [24]. In Western countries, for example, fortified foods were bought initially by the middle classes primarily, and then became more and more the foods that are bought by all. Even in countries such as the United States, there are less advantaged groups needing special programmes, such as the Women, Infants, and Children (WIC) programmes.

The main lesson up to this point has been that although simple nutritional and technological solutions to the problems of micronutrient malnutrition exist, these are often complicated by economic, social, and political factors [4, 6, 10]. Following from the above, conditions necessary for the success of food-fortification programmes include the following:

- » political will and support, which must be maintained from the developmental stage through quality assurance and control;
- » understanding of the problem by having adequate data on the magnitude of the nutritional problem being addressed;
- » adequate data on food-consumption patterns;
- » industry support with involvement of local industry and the private sector;
- » adequate technical expertise, sufficient time for the development of the food, and adequate testing under a range of real field conditions;
- » a multisectoral approach in establishing a programme, including key governmental organizations, the food industry, trade organizations, the scientific community, consumers, marketing specialists, and other relevant interested parties, early in the process;
- » adequate application of legislation and regulations, including those for external quality assurance;
- » facilitative rather than punitive regulations; i.e., guidelines should not be so restrictive as to impede the provision of high-quality fortified foods nor hinder communication on fortification between relevant parties;
- » human resource training at the industry and marketing levels and of public health and food-safety personnel;
- » appropriate fortification levels evaluated and adjusted according to the bioavailability of the nutrient in the diets of the target population;
- » good bioavailability of the compound and no constraints on procurement of the micronutrients;
- » no inhibitory effect of the common diet (and in the case of iron-deficiency anaemia and vitamin A deficiency, complementary control of parasitism, infectious diseases, and other non-dietary causes);
- » intensive and appropriate investment in information, education, and communication about the problem and the fortification approach, to ensure consumer acceptability and also to ensure that there are no cultural or other objections against fortified foods;
- » minimal cost increases to the consumer;

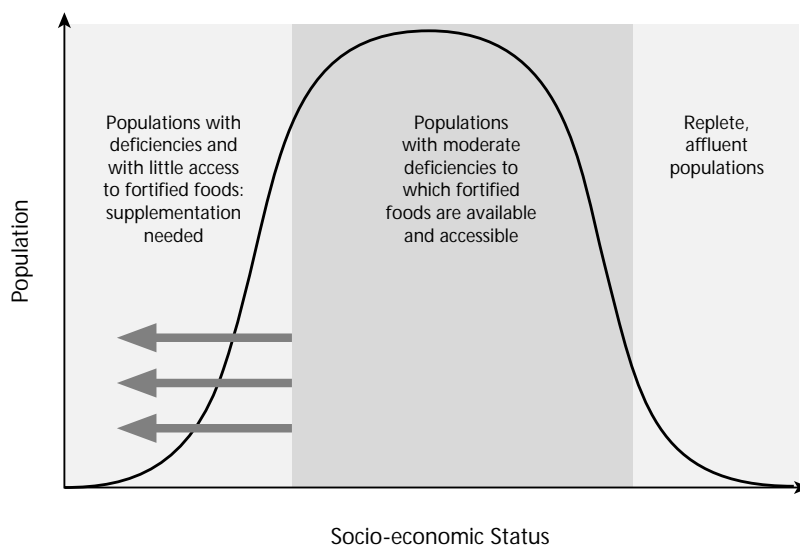


FIG. 1. Paradigm for increasing micronutrient intakes in populations with micronutrient deficiencies

» relevant nutritional information available through adequate labelling to help ensure consumer involvement, commitment, and understanding of the advantages of fortifying foods.

Summary

From recent experience and the lessons learned from it, it is clear that the attributes of a successful programme require at least the following: political will and support and the willingness to legislate or regulate; private-sector involvement; public-sector support; willingness of both sectors to enforce quality assurance; good data on consumption patterns; social acceptability of the fortified food, implying no change in organoleptic properties; and minimal increase in cost. The current situation and the existing resources and constraints need to be assessed in each country. However, fortification has clearly become a viable and cost-effective intervention for coun-

tries to adopt in their efforts to control and prevent micronutrient malnutrition.

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Technical aspects of food fortification

Moehammad Aman Wirakartakusumah and Purwiyatno Hariyadi

Abstract

The nutritional status of the population is one of the important factors determining the quality and productivity of the population, which in turn affects national productivity. In the long term, good nutritional status contributes to the intelligence and health of the population. Consequently, programmes directed at improving the nutritional status of the population will undoubtedly be a high priority in the national development scheme of any country, developed or developing. Food fortification, i.e., the addition of nutrients to specific foods based on the dietary habits and nutritional status of the target population, is one of the most popular nutritional interventions for improving the population's nutritional status. For food-fortification programmes to be successful, their technical aspects need to be carefully assessed. These include the nutritional justification for food fortification, the acceptability of the fortified food product to consumers (both cost and taste), and any technical or analytical limitation to compliance with food regulations and labeling requirements. Important technical aspects of developing effective food-fortification programmes are the choice of food carrier, nutrient interactions, bioavailability of nutrients, stability of nutrients added under anticipated conditions of storage and processing (food preparation at the household level), and safety. A good fortified product should not cause nutrition imbalance, and excessive intake of nutrients should not have adverse effects. To provide better information for the consumer, the concept of overage should be introduced. Overage is the use of kinetic data on nutrient stability to calculate the amount of added nutrient so that the anticipated level of the nutrient at the end of the product's shelf life is in accordance with the level indicated on the label.

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Mention of the names of firms and commercial products does not imply endorsement by the United Nations University.

Introduction

The nutritional status of the population is one of the important factors in determining the quality and productivity of a population, which in turn will affect national productivity. In the long run, good nutritional status contributes to the social and economic development of a nation. However, many nutritional studies, particularly in developing countries, have indicated that certain segments of the population suffer from one or more nutrient deficiencies, which can have serious effects on their health and productivity. The causes are many and varied.

As in many other developing countries, three major nutritional (especially micronutrient) deficiencies are regarded as public health problems in Indonesia: iodine-deficiency disorders, vitamin A deficiency, and iron-deficiency anaemia. The government of Indonesia has instituted programmes to cope with these three deficiencies, one of which is a food-fortification programme.

Definition of food fortification

Several terms besides fortification are used for the addition of nutrients to foods: restoration, enrichment, standardization, and supplementation [1, 2].

Restoration is the addition of a nutrient to a food in order to restore the original nutrient content. *Enrichment* is the addition of nutrients to foods in accordance with a standard of identity as defined by food regulations. Both restoration and enrichment programmes usually involve the addition of nutrients that are naturally available or present in the food product.

Standardization is the addition of nutrients to foods to compensate for natural variation, so that a standard level is achieved. Standardization is an important step to ensure a consistent standardized quality of the final product.

Supplementation is the addition of nutrients that are not normally present or are present in only minute quantities in the food. More than one nutrient may be

added, and they may be added in high quantities.

As compared with restoration and standardization, fortification has a special meaning: the nutrient added and the food chosen as a carrier have met certain criteria, so that the fortified product will become a good source of the nutrient for a targeted population. Nutrients added for food fortification may or may not have been present in the food carrier originally.

Effectiveness of food-fortification programmes

Food fortification differs from other programmes that involve the addition of nutrients to foods. Fortification is a nutritional intervention programme with a specifically defined target, and fortified food products are expected to become a main source of the specific added nutrient. Consequently, food fortification is expected to help prevent nutritional inadequacy in targeted populations in which a risk of nutrient deficiency has been identified. The criterion of the effectiveness of a food-fortification programme is whether the nutritional and health status of a targeted population has been improved.

The effectiveness of a food-fortification programme depends on whether or not the fortified food is accepted, purchased, and consumed by the targeted population. Factors such as the quality, taste, and price of the fortified products will play important roles in determining the effectiveness of the fortification programme. Several other important factors that should be considered carefully in designing food-fortification programmes are the following:

- » The food chosen as the carrier should be consumed in sufficient quantities to make a significant contribution to the diet of the targeted population. Salt, sugar, flour, monosodium glutamate (MSG), and cooking oil have been used. Other foods should be explored, especially with reference to the specific food habits and preferences of targeted populations.
- » The addition of nutrients should not create an imbalance of essential nutrients. This is especially important for doubly, triply, or multiply fortified foods, in which interaction among the added nutrients (and also among the added nutrients and the nutrients that are naturally present in the food carrier) is likely to occur.
- » The added nutrient should be stable under normal conditions of storage and use. Data on the stability of the added nutrient are also important for labelling purposes.
- » The price of the fortified food should be affordable for the targeted population.
- » Programmes of quality assurance and control of fortified food can be more easily implemented if the fortification programme is centralized and involves mass production.

- » The food should be distributed to as much of the targeted population as possible.

Nutrient stability

Nutrient stability under normal conditions of storage and use is one of the important factors determining the effectiveness of a food-fortification programme. From a technical standpoint, nutritional stability during formulation, preparation, and processing is very crucial in determining the effective production of fortified foods. The following factors relating to nutrient stability are important for the manufacturers of fortified foods [2]:

- » The technologist needs to know the extent to which food processes and distribution systems could affect nutrient retention; at the same time, the technologist needs appropriate data to develop strategies for minimizing the losses caused by nutrient instability.
- » The quality, legislative, and marketing specialists need adequate information on nutrient stability, especially to enable them to make statements or claims on labels and advertising.
- » The accountant needs to be aware of the stability data to establish and justify expenditures on potential modifications of processing techniques, the cost of nutrient premixes, etc.
- » The nutritionist needs to be aware of the stability data to assess the choices and, ultimately, the supply of nutrient(s) for consumers.

Nutrient stability is affected by physical and chemical factors. A wide range of physical and chemical factors influencing the stability of nutrients can be seen in [figure 1](#). Although many factors may cause serious nutrient degradation, measures can be developed to minimize losses by applying proper technology, which includes application of a protective coating for an individual nutrient; addition of antioxidants; control of temperature, moisture, and pH; and protection from air, light, and incompatible metals during processing and storage. In this paper, several means to reduce the magnitude of degradation will be discussed, especially with regard to vitamin A, iodine, and iron.

Vitamin A

Vitamin A is a critical micronutrient, essential for night vision and for the maintenance of skin and mucosal integrity. An early sign of vitamin A deficiency is night-blindness. Severe vitamin A deficiency may result in permanent blindness. Vitamin A deficiency is still a major nutritional problem in Indonesia as well as in many other parts of the world. The main intervention programmes against vitamin A deficiency administered by the Indonesian government are nutrition education, distribution of vitamin A capsules, and fortification of selected widely consumed foods.

Fortification of foods with vitamin A has been shown to be a very promising strategy. A pilot project on vitamin A fortification of monosodium glutamate (MSG) in three provinces has resulted in reduction of the prevalence of vitamin A deficiency. Further developments are dependent on overcoming the colour changes caused by fortification of MSG with vitamin A. Other foods, such as palm oil and noodles, have also been considered as carriers for vitamin A.

Vitamin A occurs in many forms, such as retinol (alcohol), retinal (aldehyde), retinyl acetate or retinyl palmitate (esters), and provitamin A carotenoids (β -carotene, α -carotene, etc.). Vitamin A is relatively unstable under normal storage conditions, particularly in harsh environments. The instability is mostly due to its chemical structure, which contains many double bonds susceptible to degradation (fig. 2).

To minimize the degradation of vitamin A, several approaches have been introduced. Since vitamin A is sensitive to atmospheric oxygen (the alcohol form of vitamin A is less stable than the esters), it is normally available commercially as a preparation protected by a coating that includes antioxidant(s). According to Murphy [3], there has been only one major supplier of vitamin A (as retinyl palmitate or acetate) for food fortification, Hoffman-La Roche of Switzerland. Table 1 lists the major formulations that are or have been available.

Antioxidants that may be added to vitamin A premixes

are butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), and α -tocopherols (vitamin E). The use of vitamin E as an antioxidant is gaining popularity. Trace metals (especially iron and copper) and ultraviolet light accelerate the degradation of vitamin A. The stability of vitamin A is also affected by acidity. Below a pH of 5.0, vitamin A is very unstable.

Iron and iodine

Iron deficiency is the most widespread nutritional problem in the world. In Indonesia the prevalence of anaemia among pregnant women, children under five years of age, and women workers is 64%, 55%, and 30%, respectively. Iron deficiency has adverse effects on resistance to infection, morbidity and mortality from infectious disease, learning processes, behaviour, physical condition, and productivity.

One important factor that should be carefully assessed in the preparation of mineral premixes (as ingredients for food fortification) is the type of salt to be fortified. Iron is usually supplied in the form of ferric phosphate, ferric pyrophosphate, ferric sodium pyrophosphate, ferrous gluconate, ferrous lactate, ferrous sulphate, or reduced iron (table 2), whereas iodine is normally supplied in the form of potassium iodide or iodate.

The following chemical and physical factors should be checked thoroughly in the formulation for food for-

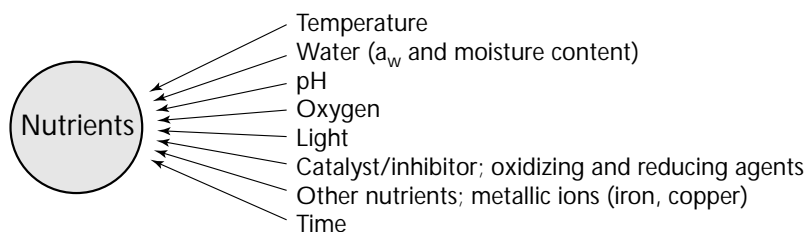


FIG. 1. Factors influencing the stability of nutrients

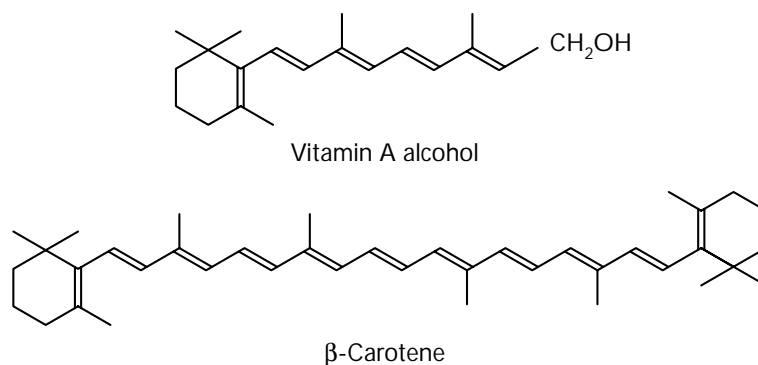


FIG. 2. Chemical structure of vitamin A alcohol and β -carotene

TABLE 1. Commercial vitamin A preparations available from Hoffman-La Roche

Type	Ingredients	Food application
250 CWS	Retinyl palmitate, acacia, sugar, modified food starch, BHT, BHA, sodium benzoate, α -tocopherol	Non-fat dry milk, dehydrated foods, dry cereals, beverage powders to be reconstituted before use
250 S	Retinyl palmitate, gelatin, sorbitol-modified food starch, sodium citrate, corn syrup, ascorbic acid, coconut oil, BHT, α -tocopherol, silicon dioxide, BHA	Dry mix and fluid milk products
250 SD	Retinyl palmitate, acacia, lactose, coconut oil, BHT, sodium benzoate, sorbic acid, silicon dioxide, BHA	Foods and baked products, dehydrated potato flakes, dry milk
500	Retinyl palmitate, gelatin, invert sugar, tricalcium phosphate, BHT, BHA, sodium benzoate, sorbic acid, sodium bisulphite	Dry mix and fluid milk products
Emulsified RP	Sucrose-retinyl palmitate emulsion in water	Tea leaves
Oil	Retinyl palmitate, BHA, BHT	None

Source: ref. 4.

Abbreviations: BHT, butylated hydroxytoluene; BHA, butylated hydroxyanisole; CWS, cold water soluble; RP, retinyl palmitate.

TABLE 2. Selected iron sources currently used in food fortification

Compound	Other common name	Formula	Iron content (g/kg)	RBV ^a
Ferric phosphate	Ferric orthophosphate	$\text{FePO}_4 \cdot x\text{H}_2\text{O}^b$	280	3–46
Ferric pyrophosphate	Iron pyrophosphate	$\text{Fe}_4(\text{P}_2\text{O}_7)_3 \cdot 9\text{H}_2\text{O}$	250	45
Ferric sodium pyrophosphate	Sodium iron pyrophosphate	$\text{FeNaP}_2\text{O}_3 \cdot 2\text{H}_2\text{O}$	150	14
Ferric ammonium citrate		$\text{Fe}_x\text{NH}_3(\text{C}_6\text{H}_8\text{O}_7)_x$	170	107
Ferrous fumarate		$\text{Fe}(\text{C}_4\text{H}_2\text{O}_4)$	330	95
Ferrous gluconate		$\text{Fe}(\text{C}_6\text{H}_{12}\text{O}_7)_x^c$	120	97
Ferrous lactate		$\text{Fe}(\text{C}_3\text{H}_5\text{O}_3)_2 \cdot 3\text{H}_2\text{O}$	380	—
Ferrous sulphate		$\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$	320	100 ^c
Iron	Elemental iron, ferrum reductum, metallic iron	Fe	1,000	
Reduced iron, H ₂ or CO process		Fe	960	34
Reduced iron, electrolytic		Fe	970	50
Reduced iron, carbonyl		Fe	980	67

Source: ref. 4.

a. RBV denotes relative biological value. Iron-deficient rats are cured of iron deficiency by feeding them either a test iron sample or a reference dose of ferrous sulphate. The cure is measured by haemoglobin or packed-cell volume repletion in the rats' blood, and the bioavailability of the samples is reported against a value of 100 for ferrous sulphate. Thus, any iron sample that is less available than ferrous sulphate will have an RBV of less than 100.

b. Ferric orthophosphate contains from one to four molecules of hydration.

c. The precise structures of the iron salts are uncertain.

tification, especially for iron:

- » Solubility: ferrous salts are more soluble than ferric salts.
- » Oxidative state: ferrous salts can be utilized more efficiently than ferric salts; however, ferrous salts are also more reactive in food systems.
- » Ability to form complexes: ferric iron generally has

a greater tendency to form complexes than ferrous iron; the formation of complexes will greatly reduce iron bioavailability.

In the preparation of iron as an ingredient for food fortification, the possibility that the iron will react or associate with other nutrients needs to be explored. The presence of metal ions (such as iron) may have a det-

rimental effect on quality if measures are not properly taken. Iron has been shown to speed up vitamin degradation (especially vitamins A and C and thiamine), catalyse the oxidative rancidity of oils and fats, and produce undesirable changes (colour, off flavours, etc.)

Effect of processing on the stability of added nutrients

The stability of nutrients is affected by many chemical and physical factors (fig. 1). Consequently, processing parameters must be selected and controlled during the processing of fortified food to minimize nutrient losses.

Compared with vitamins, minerals (iron and iodine) are very stable under extreme processing conditions. The primary mechanism of loss of minerals is through leaching of water-soluble materials [1]. Vitamin A, on the other hand, is very labile in the processing environment. Figure 3 illustrates the possibilities for the degradation of vitamin A (especially in its provitamin form β -carotene). Vitamin A is both oxygen and temperature sensitive. Borenstain [6] and Ottaway [7] have both reported that vitamin A (and also β -carotene) added to foods is sensitive to oxidative damage. In the form of retinol, vitamin A is more labile than its ester form; for this reason, vitamin A esters are usually used for food fortification, as illustrated by the list in table 1.

Table 3 shows the stability of vitamin A in pasteurized, multivitamin-supplemented orange juice. Vitamin A was slightly degraded during the first two months of storage. Vitamin A activity was much more stable when the vitamin was added as β -carotene.

The stability of vitamin A is also strongly affected by pH. At a pH of less than 5, vitamin A is susceptible to oxidation. At low pH, vitamin A tends to isomerize from the *trans* to the *cis* configuration, which has a lower vitamin activity. The problem of low pH is encountered especially during juice processing. Fruit juices usually have a low pH (about 3.0). To compensate for low pH, carbonation, which expels oxygen, may be used to stabilize vitamin A.

TABLE 3. Degradation of vitamin A during processing and storage of pasteurized, multivitamin-supplemented orange juice

Form of vitamin A	Amount of vitamin A— IU/100 ml (% of initial value)			
	Added	Total initial	2 mo	6 mo
Retinol	219	232 (100)	168 (72)	163 (70)
β -Carotene	175	191 (100)	203 (100)	180 (94)

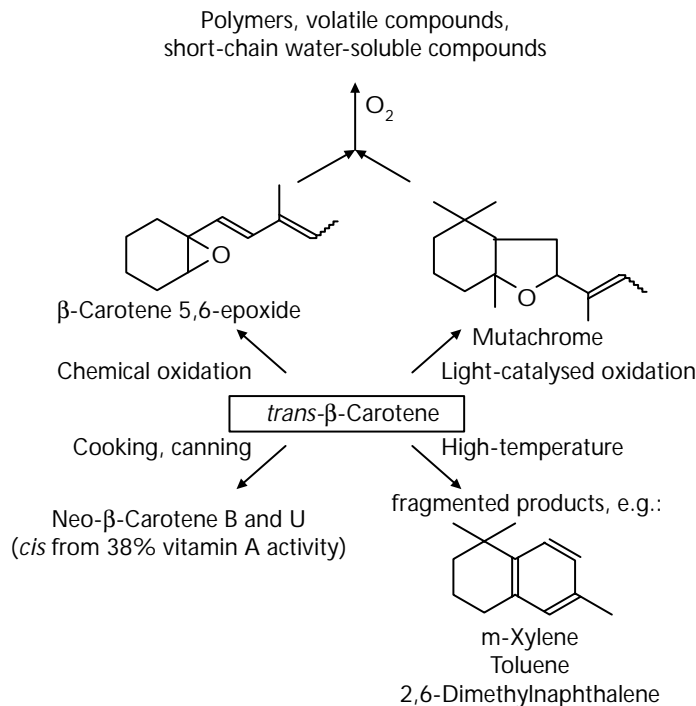


FIG. 3. Degradation pathway of β -carotene [5]

Effect of high-temperature treatment on nutrient (vitamin) stability

Because high temperatures may be used in the manufacture of fortified foods, measures must be taken to minimize losses from thermal degradation. Drying is a processing method that uses high temperatures, and it has many applications in the manufacturing of fortified food. Drying is usually performed using several combinations of time and temperature, such as 9 to 12 hours at 50°C, 2 to 3 hours at 95°C, or 2 to 5 seconds at 140°C. To minimize nutrient losses, the use of lower combinations of time and temperature is desirable, which can be achieved by either increasing the surface area or reducing the pressure during the drying process.

Oven drying is the most common method. Pasta products, for example, may be dried in an oven for 9 to 12 hours at 50°C or for 2 to 3 hours at 95°C. O'Brien and Robertson [8] reported that β -carotene was more stable than the ester form of vitamin A during oven drying. During the processing of macaroni, oven drying for 9 to 12 hours at 50°C resulted in a 14% loss of vitamin A. However, the same treatment caused the loss of only approximately 5% of β -carotene. Furthermore, drying for 3 to 5 hours at 95°C caused the destruction of 23% of vitamin A but only 8% of β -carotene.

Drum drying is often used for manufacturing fortified food in powdered form. The advantage of drum drying over conventional oven drying is that higher temperatures can be used with a processing time of only 2 to 30 seconds. The combination of high temperature and short time (HTST) maximizes nutrient retention.

Furthermore, the drum dryer is usually used for liquid food slurries. Hence, the material may reach a very high temperature as it forms a film over the drum surface. The formation of this film during drying may offer some protection to the nutrients from oxidative damage, especially in comparison with similar HTST processes, such as the extrusion process. Table 4 shows that the retention of nutrients is much better during drum/roller drying than extrusion processing because of the film formation [8].

Spray drying is another technique that can be used for manufacturing fortified food. Besides time-temperature combinations, other measures to prevent or minimize the contact of sprayed food products with oxygen need to be applied. During spray drying, a fine spray of food is introduced into the drying chamber where it encounters a stream of hot air, which produces rapid drying. The spraying process greatly increases the contact of the food with oxygen, thus accelerating oxidative damage.

Several ways to minimize oxidative damage have been introduced, including the addition of antioxidants and the application of coating materials and capsulation. Coating material can be applied by using sucrose in a raw material formulation. Johnson et al. [9] showed

TABLE 4. Vitamin losses: extrusion vs. roller drying

Losses	Vitamin A	Vitamin C
Quantity added per 100 g dry material	2,932 IU	71.8 mg
Loss with extrusion (%)		
Process loss	62.4	8.2
Storage loss		
6 mo	75.0	31.1
12 mo	85.3	45.2
Loss with roller drying (%)		
Process loss	26.2	9.2
Storage loss		
6 mo	39.2	24.2
12 mo	60.6	37.0

Source: ref. 8.

that a coating containing at least 10% sucrose was needed to offer good protection from oxidative attack during spray drying. They also noted that, if possible, addition of 15% to 20% of sucrose to the raw material formulation is desirable, since it offers greater protection from oxidation.

To minimize the deterioration caused by oxidation during drying, nutrients may be added after drying. This has been done in milk fortification, in which dry premixes containing the nutrient at the desired level were used. This process (fig. 4) is relatively simple and efficient, but requires extra mixing equipment.

Another food-processing operation that uses high temperatures is the extrusion process. Extrusion is very popular for manufacturing snack foods and ready-to-eat breakfast cereals. Extrusion has several advantages over other methods, since it is a very versatile process that includes several operations at once: mixing, cooking, and forming. Several parameters are important in determining the quality of the final product, including temperature (100° to 140°C or higher), moisture content, coating system, and oxygen, as well as other parameters characteristic of the extrusion process, such

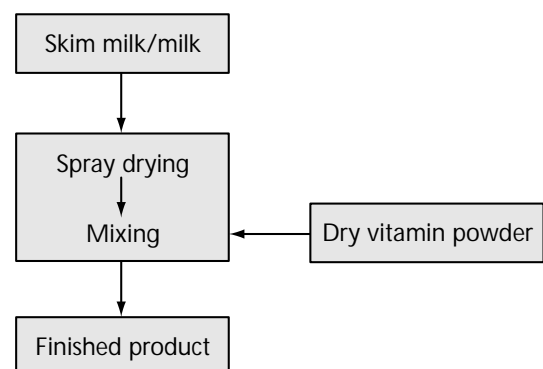


FIG. 4. Fortification of spray-dried milk with vitamins

as pressure, throughput rate, velocity (rpm) of the screw, and die diameter [10]. If possible, fortification should be done during the final process in order to maximize nutrient retention. At this stage, fortification can be carried out during application of flavour.

Stability of nutrients and proper labelling

Increased consumer awareness of healthy eating has forced food producers to disclose information about the composition of their products on the label. With fortified foods, the amount of the added nutrient declared on the label is very important.

To meet label claims within a realistic shelf life, manufacturers must study the behaviour and kinetics of nutrient degradation thoroughly. To make correct claims about the nutrient content of a product on its label, the amount of the added nutrient should actually be more than that amount stated or declared on the label. The difference between the formulated and the declared levels is known as overage. $Overage = (\text{amount of nutrient present in the product} - \text{amount declared on the label}) / \text{amount declared on the label} \times 100$.

The overage will vary according to the inherent stability of the nutrients, the conditions under which the food is prepared and packaged, and the anticipated shelf life of the product. Thus, the more labile or unstable nutrients, such as vitamin A, generally require high overages. Table 5 shows examples of vitamin A overages used in three different products. An overage of 25% means that if the declared amount of vitamin A is, for example, 20 mg per gram of product, then the input level or the amount of nutrient in the formulation should be 25 mg per gram of product.

The shelf life and the declared amount of a nutrient on the label (based on the amount of the nutrient remaining at the end of a product’s shelf life) can be determined by several methods, one of which is Arrhenius’ method as described by Labuza and Riboh [11].

The kinetics of nutrient degradation can be modelled as zero or first-order kinetics [12]. Using a simple kinetic model [11, 12], we can predict the shelf life and the overages of a particular nutrient. Table 6 compares the nutrient losses predicted by Arrhenius’ model with the actual amounts lost.

Another aspect of labelling of fortified foods is the claim for nutrients. In the United Kingdom, for ex-

ample, if a claim is made on the label that a food is a “rich” or “excellent” source of a particular vitamin or mineral, the daily food portion (described as “the quantity of food that can reasonably be expected to be consumed in a day”) must contain at least half of the recommended dietary allowance (RDA) for that nutrient [2]. For the requirements of other countries, specific food laws and regulations should be consulted.

Conclusion

Food fortification is a nutritional intervention programme with a specifically defined target population, and its effectiveness is measured by whether or not the fortified food is accepted, purchased, and consumed by that population. The success of a food-fortification programme is measured by whether or not the nutrition and health status of the targeted population has been improved. Therefore, several important aspects should be carefully assessed in the development of a food-fortification programme, such as determining nutrient stability under normal conditions of storage and use. From the technical point of view, nutritional stability during formulation, preparation, and processing is crucial for the effective production of fortified foods.

Many factors may cause serious nutrient degradation. Consequently, the proper technology to minimize losses needs to be implemented. Some strategies for stabilizing nutrient content include the application of protective coating for the individual nutrient; the addition of antioxidants; the control of temperature, moisture, and pH; and protection from air, light, and incompatible metals during processing and storage.

The stability of nutrients and the conditions under which fortified foods are prepared, manufactured, and packaged will affect the shelf life of the product and, concomitantly, the nutrient overages. The degree of nutrient degradation in food and the length of the shelf life will govern the level of overage. The degree of nutrient degradation can be determined by several methods, one of which is the relatively simple Arrhenius method, which can be used to predict the shelf life and the overages of a particular nutrient.

TABLE 5. Vitamin A overages in three products

Product	Shelf life (mo)	Overage (%)
Milk-based fortified drink powder	12	25
Fortified meal replacement bar	12	45
Multivitamin tablet	30	60

TABLE 6. Vitamin losses (%) after six months of storage at 20°C and 75% relative humidity

Vitamin	Predicted from Arrhenius’ model	Analysed after storage
Vitamin C	24.0	23.0
Vitamin A preparation	15.0	10.0
Folic acid	8.1	7.4
Vitamin B ₁₂	9.2	7.7

Source: ref. 11.

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Food fortification: Safety and legislation

Gregory D. Orriss

Abstract

The Food and Agriculture Organization/World Health Organization (FAO/WHO) International Conference on Nutrition (ICN), held in Rome in December 1992, recognized the widespread occurrence of micronutrient deficiencies, particularly in developing countries. The conference recognized food-based approaches as the most effective way to address existing micronutrient deficiencies. These approaches must include appropriate strategies to assure dietary diversification, improved food availability, food preservation, nutrition education, and food fortification.

The final report of the conference included strategies and actions for preventing and controlling specific micronutrient deficiencies. It was proposed to ensure and legislate the fortification of foods or water with necessary micronutrients, where possible, when existing supplies fail to provide adequate levels in the diet. Food fortification has been successfully used in both developed and developing countries as one strategy to address micronutrient deficiencies.

The primary purposes of food legislation are to protect the health of the consumer, protect the consumer from fraud, and facilitate trade. In the case of fortified foods, the target population must be protected from receiving either toxic or nutritionally ineffective levels of micronutrients. Legislation may be necessary to require adequate control over this fortification process by the food processors to ensure that levels of micronutrients are consistently within acceptable limits. Legislation may also be required to prohibit the addition of nutrients to commodities where it is nutritionally unnecessary or unsafe or where fortification may create an erroneous impression as to the nutritional value of the food.

Any legislation regarding food fortification should incorporate the standards, recommendations, and guide-

lines of the Codex Alimentarius. The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) and the WTO Agreement on Technical Barriers to Trade (the TBT Agreement) have placed new importance on Codex standards, guidelines, codes, and recommendations.

Introduction

FAO/WHO International Conference on Nutrition

The Food and Agriculture Organization/World Health Organization (FAO/WHO) International Conference on Nutrition (ICN), held in Rome in December 1992, recognized the widespread occurrence of micronutrient deficiencies [1]. The conference's World Declaration and Plan of Action for Nutrition recommended steps to eliminate iodine and vitamin A deficiencies before the end of this decade and to reduce substantially other important micronutrient deficiencies, including iron deficiency.

The ICN recognized food-based approaches as the most sustainable way to address existing micronutrient deficiencies. These approaches must include strategies to assure dietary diversification, improved food availability, food preservation, nutrition education, and food fortification. Existing constraints in many developing countries include agricultural, economic, environmental, sociocultural, political, health-related, and infrastructural issues. In every case, the most appropriate combination of the above-mentioned nutrition strategies must be employed to overcome local constraints and achieve the desired results. It was widely recognized that the long-term solution to micronutrient deficiencies must rest on the provision of adequate quantities of all micronutrients from a well-balanced diet.

The ICN Strategies and Actions related to the prevention and control of micronutrient deficiencies included the following strategy for food fortification: "Ensure and legislate for the fortification of foods or water with necessary micronutrients when feasible, when

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existing food supplies fail to provide adequate levels in the diet.”

World Food Summit

The World Food Summit, held in Rome 13-17 November 1996, adopted the Rome Declaration on World Food Security and the World Food Summit Plan of Action [2], which laid the foundations for diverse paths to a common objective of food security at the individual, household, national, regional, and global levels. Food security exists when people, at all times, have physical and economic access to meet their dietary needs and food preferences for a healthy lifestyle.

Objective 2.3 of the World Food Summit Plan of Action is “to ensure that food supplies are safe, physically and economically accessible: appropriate and adequate to meet the energy and micronutrients needs of the population.” This objective includes the provision that governments, in partnership with all sectors of civil society, as appropriate, will “implement the goals of preventing and controlling specific micronutrient deficiencies as agreed by the ICN.”

International environment affecting trade in food

Agreement on Sanitary and Phytosanitary Measures

The Uruguay Round of Multilateral Trade Negotiations, which began in Punta del Este in September 1986, concluded in Marrakech in April 1994 [3]. The Marrakech Agreement established a new World Trade Organization (WTO) to succeed the General Agreement on Tariffs and Trade (GATT). The Uruguay Round negotiations were the first to deal with the liberalization of trade in agricultural products, an area excluded from previous Rounds of negotiations. The Uruguay Round also included negotiations on reducing non-tariff barriers to international trade in agricultural products and concluded with two binding Agreements: the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) and the Agreement on Technical Barriers to Trade (the TBT Agreement). The Agreements will be applied by members of the WTO.

The SPS Agreement confirms the right of WTO member countries to apply measures necessary to protect human, animal, and plant life and health. This right was included in the original 1947 General Agreement on Tariffs and Trade as a general exclusion from the other provisions of the Agreement, provided that “such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.” Despite this general condition for the application of

national measures to protect human, animal, and plant life and health, it had become apparent by the time of the Punta del Este Declaration that national sanitary and phytosanitary measures had become, whether by design or accident, effective trade barriers.

The SPS Agreement, therefore, sets new rules in an area previously excluded from GATT disciplines. The purpose of the SPS Agreement is to ensure that measures established by governments to protect human, animal, and plant life and health in the agricultural sector only are consistent with obligations prohibiting arbitrary or unjustifiable discrimination on trade between countries where the same conditions prevail, or which are a disguised restriction on international trade. It requires that, with regard to food-safety measures, WTO members base their national measures on international standards, guidelines, and other recommendations adopted by the FAO/WHO Codex Alimentarius Commission where they exist, except that they may adopt stricter measures if there is a scientific justification for doing so or if the level of protection afforded by the Codex standard is inconsistent with the level of protection generally applied and deemed appropriate by the country concerned. The SPS Agreement covers all food-hygiene measures and food-safety measures, such as the control of residues of veterinary drugs, pesticides, or other chemicals used in meat production.

The SPS Agreement states that any measures taken that conform to international Codex standards, guidelines, or other recommendations are deemed to be appropriate, necessary, and non-discriminatory. Furthermore, the SPS Agreement calls for a programme of harmonization of national requirements based on international standards. This work is guided by a WTO Committee on Sanitary and Phytosanitary Measures to which representatives of Codex Alimentarius, the Office International des Epizooties (OIE), and the International Plant Protection Convention (IPPC) are invited.

Agreement on Technical Barriers to Trade

The TBT Agreement is a revision of the Agreement of the same name first developed under the Tokyo Round of GATT Negotiations in the 1970s. Examples given in the TBT Agreement of legitimate TBT measures are those the objectives of which are national security and the prevention of deceptive practices. The objective of the Agreement is to prevent the use of national or regional technical requirements, or standards in general, as unjustified technical barriers to trade. It covers all types of standards, including quality requirements for foods, *except requirements related to sanitary and phytosanitary measures*, and includes a very large number of measures designed to protect the consumer against deception and economic fraud. The Agreement basically provides that all technical standards and regula-

tions must have a legitimate purpose and that the impact or cost of implementing the standard must be proportional to the purpose of the standard. It also states that if there are two or more ways of achieving the same objective, the least trade-restrictive alternative should be followed. The TBT Agreement also places emphasis on international standards, WTO members being obliged to use international standards or parts thereof except where the international standard would be ineffective or inappropriate in the national situation. The TBT Agreement does not include a programme of harmonizing national standards.

Codex Alimentarius Commission

The Codex Alimentarius Commission was established by FAO in 1961. Since 1962 it has been responsible for implementing the Joint FAO/WHO Food Standards Programme, the primary aims of which are protecting the health of the consumer and ensuring fair practices in the food trade. The Codex Alimentarius Commission is an intergovernmental body, with 154 member governments. The Codex Alimentarius itself is a collection of food standards, codes of practice, and other recommendations presented in a uniform way [4]. Codex Alimentarius means "Food Code" or "Food Law" in Latin. Codex standards, guidelines, and other recommendations ensure that food products are not harmful to the consumer and can be traded safely between countries.

Food-safety standards are defined in the SPS Agreement as those relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice. As mentioned above, Codex food-safety standards are to be used as the reference point for the WTO in this area. Over the years, the Codex Alimentarius Commission has established maximum residue limits for 182 agricultural and veterinary chemicals, 39 codes of hygienic and good manufacturing practice, and 227 Codex standards. It has evaluated over 700 chemicals proposed for food-additive uses and established guideline levels for a number of environmental and industrial contaminants in foods, including radionuclides.

Food hygiene has been a major activity of the Codex since its establishment. The Codex Committee on Food Hygiene is hosted by the government of the United States and has held 27 sessions since 1963. Because food hygiene is best regulated at the production and processing stage in the exporting country, the Committee's main outputs have been Codes of Hygienic Practice rather than end-product microbiological standards. The Codex Alimentarius Commission has been actively revising much of its work in recent years to stress the so-called horizontal aspects of food regulation, including food hygiene. New considerations, such as risk analysis and the determination of equivalence in different

food-control systems, have an impact on the new approach to international food-hygiene regulations.

Codex and food fortification

The following standards, guidelines, and codes of practice adopted by the Codex Alimentarius Commission should specifically be considered in the development of national legislation regarding food fortification [4]:

- » Codex General Principles for the Addition of Essential Nutrients to Foods (GL 9-1987)
- » Codex General Standard for the Labelling of Pre-packaged Foods [Codex Stan 1-1985 (Rev. 1-1991)]
- » Codex General Standard for the Labelling and Claims for Pre-packaged Foods for Special Dietary Uses (Codex Stan 146-1985)
- » Codex General Guidelines on Claims (CAC/GL 1-1979 Rev. 1-1991)
- » Codex Guidelines on Nutritional Labelling (CAC/GL 2-1985)
- » Recommended International Code of Practice: General Principles of Food Hygiene [CAC/RCP 1 (Rev. 2-1985)]
- » Guidelines on the Application of the Hazard Analysis Critical Control Point (HACCP) System (CAC/GL 18-1993)

Trends in food-hygiene regulation

Hazard Analysis Critical Control Point system

The need for a more formal approach to the process of controlling hazards has been recognized by the Codex. In adopting the Codex Guidelines on the Application of the Hazard Analysis Critical Control Point (HACCP) system in 1993, the Codex Alimentarius Commission acknowledged that the HACCP system was the most cost-effective method devised to date for controlling food-borne hazards (GL-1993)[4].

HACCP is a system that identifies specific hazards as well as preventive measures for their control. The seven principles of HACCP, as adopted by the Codex, establish the framework for developing specific HACCP plans for each combination of food product and production line. When a specific HACCP plan is being developed, the identification of all potential hazards which are "of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food" is required. However, the determination of which potential hazards are "essential" to control will involve a risk-based hazard assessment. This hazard assessment will result in a list of the significant hazards that should be addressed within the HACCP plan. In the specific area of food hygiene, the Codex Alimentarius Commission is revising its main document "Recommended International Code of Prac-

tice: General Principles of Food Hygiene” to incorporate risk-assessment principles and to include specific references to the HACCP system.

The application of HACCP as public policy requires defining the role of governments in the use of the HACCP process. Recent moves by some importing countries to require application by exporting countries of HACCP principles to food produced for export will result in significant trade barriers for countries unable to meet these requirements.

Other quality assurance systems

HACCP is a quality assurance system directed to the control of hazards in foods. A wider quality control system is available through the use of the ISO 9000 series of quality control. The ISO 9000 system can be used to assure the quality of both goods (products) and services.

The ISO 9000 systems are used to transfer the assurance of quality to different partners in the sequence of food processing. For example, food-packaging materials can be purchased by the food processor on the basis of quality assurance certification from the supplier. However, the use of the ISO 9000 system in the food industry is generally controversial, as it is frequently too costly for small-scale food processors to implement effectively. Also, because the ISO 9000 series provides quality assurance for the totality of the quality attributes of a food product, it goes beyond the basic regulatory requirements of ensuring that food is safe and properly labelled and presented to the consumer. Regulators are, therefore, content to insist on the application of the HACCP system to meet national and international food regulations.

Sampling and analysis at import

Risk-based inspection

When a consignment of food arrives at the point of import, national food authorities are normally required to verify that the food is in conformity with national food regulations before the consignment receives customs clearance and is released to the importer. The inspector is faced with several options, which range from the inspection of all consignments to the use of a random inspection system. It is generally recognized that the inspection of all food consignments is too costly (especially in terms of laboratory resources) and can result in loss if the food is perishable. Random inspection procedures, even if soundly based on statistics, will result in directing efforts too diffusely, with the result that foods known to be the source of risks will escape inspection.

More attention is being paid internationally to risk-based inspection systems (targeting certain foods or

hazards on the basis of the likelihood of risk). Some countries have formalized this approach and categorize imported foods as having high, medium, or low risk, assigning their inspection resources accordingly. In these systems, exporters are also categorized on the basis of their ability to conform to the importing country's requirements.

The idea of risk-based import inspection systems is incorporated into the Codex Principles for Import and Export Inspection and Certification, adopted by the Codex Alimentarius Commission in July 1995. More precise guidelines for practical application are in the course of development by the Codex Committee on Food Import and Export Inspection and Certification Systems.

Equivalence of inspection systems

The Uruguay Round SPS Agreement calls for the recognition of “equivalence” in the application of sanitary and phytosanitary measures. At a basic level, this means that the exporting country need not apply the same regulations for processing and production as are required in the importing country, provided that the outcome of the regulatory process is the same in terms of assuring the safety of the food product. The same concept applies to the inspection systems used by the two countries. The impact of this decision has special relevance for food hygiene, in which inspectors are required to exercise a high degree of judgement and for which countries have frequently adopted quite diverse systems for the selection, education, and training of inspectors.

The SPS Agreement places the responsibility for demonstrating equivalence on the exporting country, and the WTO Committee on SPS Measures is currently considering how such “equivalence” should be determined. Equivalence of inspection systems is also incorporated into the Codex Principles for Import and Export Inspection and Certification, and the concept will be developed further by the Codex Committee.

Certification control and bilateral agreements

Risk-based inspection and the recognition of equivalence in inspection systems lead to a consideration of certification procedures and the acceptability of certificates issued by national export authorities. If an exporting country is recognized as being able to provide an equivalent inspection system, then goods accompanied by a certificate issued by the exporting authorities should be subject to less frequent inspections than would otherwise be the case. This has the multiple benefit for the importer of releasing resources for inspection of other, higher-risk consignments and providing a better assurance of safety, especially if the certificate indicates that a full in-process safety-control system, such

as HACCP, has been used. For the exporter, it means better and quicker access to the importing country's market. The same objectives can be achieved through bilateral agreements that establish mutually acceptable inspection procedures (providing equivalent health protection) but do not require the individual certification of consignments.

Hygiene certificates have been in use for some time, but their acceptability is highly variable, depending on the issuing authority. The Codex Committee on Food Import and Export Certification and Inspection Systems is preparing guidance for governments in developing certification systems that should meet the requirements of importers. It is also considering guidelines for the overall scope and content of bilateral agreements covering the same area.

Methods of analysis

Analytical procedures used in food inspection have undergone changes similar to those effected in the inspection process itself. The Codex Committee on Methods of Analysis and Sampling, working in close cooperation with the International Organization for Standardization (ISO), AOAC International, and the International Union for Pure and Applied Chemistry (IUPAC), is recommending protocols for determining the reliability of analytical test methods and the results of laboratory analyses. Here, also, there is a trend towards recognizing the equivalence of different test methods that obtain reliable results, thus allowing laboratories to use the method of their choice, depending on local considerations.

FAO technical consultation on food fortification: Technology and quality control

The Food and Agriculture Organization (FAO) of the United Nations convened a Technical Consultation on Food Fortification: Technology and Quality Control in Rome, 20-23 November 1995 [5]. The following practical problems were discussed.

With the expanding range of fortificant compounds available and the need to use various vehicles according to the designated target groups, it is necessary to consider the technologies best suited to achieve a fortified product with the desired properties. The Consultation agreed that, ideally, a fortified food should:

- » be commonly consumed by the target population;
- » have a constant consumption pattern with a low risk of excess consumption;
- » have good stability during storage;
- » be relatively low in cost;
- » be centrally processed, with minimal stratification of the fortificant;

- » have no interaction between the fortificant and the carrier food;
- » be contained in most meals, with the availability unrelated to socio-economic status;
- » be linked to energy intake.

Selection of an appropriate vehicle is a critical step in successful fortification. In many cases, identification of suitable vehicles is made difficult by the absence of reliable information on dietary habits.

The desirability of providing detailed methodologies for the fortification of foods to countries with limited resources interested in carrying out such activity was recognized. In recognition of the fact that the need for information on technical procedures in the fortification of foods still exists, the consultation recommended that a database documenting fortification practices and new developments be established and maintained. This should facilitate ready access to such information internationally, thus reducing wastage of resources and improving efficiency in the establishment of food fortification.

Important lessons learned in the technical research and development work carried out for food fortification processes include the following:

- » The long time and high cost required for the development of new combinations of fortificants and vehicles must be considered in planning fortification activity;
- » Fortificants must meet quality criteria specifications explicitly established for each application, including chemical stability, appearance, bioavailability, and homogeneity;
- » Field testing of fortified food must be done at several locations in the country of intended fortification use, due to differing environmental conditions, and consideration should be given to problems potentiated by scaling up production activities from pilot to industrial scale;
- » In certain situations, promotion of the production and consumption of fortified foods has proven to be a critical factor influencing the acceptability of the food.

Active participation must be maintained by all partners involved in fortification programmes. These should include relevant governmental organizations, food industry, trade organizations, consumer organizations, academic and research facilities, and marketing and interested international organizations and agencies.

General principles for addition of nutrients to foods

At the present stage of world trade development, international provisions pertaining to the addition of nutrients to foods are necessary in order to facilitate trade in such products. Within the FAO/WHO Food

Standards Programme, the Codex Alimentarius Commission has adopted "General Principles for the Addition of Essential Nutrients to Foods" (GL09-1991) [4]. According to these general principles, essential nutrients may be added to food in order to achieve any of the following: restoration of nutrients lost during processing, nutritional equivalence of substitute foods, fortification, and ensuring the appropriate nutrient composition for a special-purpose food. The following are the basic principles for the addition of essential nutrients to foods, as stated by the Codex Alimentarius Commission:

- » The essential nutrient should be present at a level which will not result in either an excessive or an insignificant intake of the added essential nutrient considering amounts from other sources in the diet;
- » The addition of an essential nutrient to a food should not result in an adverse effect on the metabolism of any other nutrient;
- » The essential nutrient should be sufficiently stable in the food under customary conditions of packaging, storage, distribution, and use;
- » The essential nutrient should be biologically available from the food;
- » The essential nutrient should not impart undesirable characteristics to the food and should not unduly shorten the food's shelf life;
- » Technology and processing facilities should be available to permit the addition of the essential nutrient in a satisfactory manner;
- » Addition of essential nutrients should not be used to mislead or deceive the consumer as to the nutritional merit of the food;
- » The additional cost should be reasonable for the intended consumer;
- » Methods of measuring, controlling, and/or enforcing the levels of added essential nutrients in the foods should be available;
- » When provision is made in food standards, regulations, or guidelines, for the addition of essential nutrients to foods, specific provisions should be included identifying the essential nutrients which are to be considered or required and the levels at which they should be present in the food to achieve their intended purposes.

The Codex definition of fortification is "the addition of one or more essential nutrients to a food, whether or not it is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups." Within the above general principles outlined by the Codex, nutrient addition for purposes of fortification should be the responsibility of national authorities, since the kinds and amounts of essential nutrients to be added and foods to be fortified will depend upon the particular nutritional problems to be corrected, the characteristics of the target

populations, and the food-consumption patterns in the area. Any fortification programme should, therefore, meet the following conditions:

- » There should be a demonstrated need for increasing the intake of an essential nutrient in one or more target groups. This may be in the form of actual clinical or sub-clinical evidence of deficiency, estimates indicating low levels of intake of nutrients, or possible deficiency likely to develop because of changes taking place in food habits;
- » The food selected as a vehicle for the essential nutrient should be consumed by the population at risk;
- » The food selected as a vehicle for the essential nutrient should be stable and uniform, and the lower and upper levels of intake should be known;
- » The amount of the essential nutrient added to the food should be sufficient to correct or prevent the deficiency when the food is consumed in normal amounts by the population at risk;
- » The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.

Conclusions and recommendations of the consultation

Food fortification is an essential element in nutrition strategies to alleviate micronutrient deficiencies. It is a dynamic area developing in response to the needs of population groups and industry. Efforts should continue to develop new and improved systems of delivering micronutrients to target populations through appropriate fortification procedures. To facilitate this, those involved in the establishment of food-fortification programmes locally must have ready access to information concerning fortification techniques and procedures being used all over the world. A multidisciplinary approach is essential for successful fortification, with active collaboration of all sectors involved, including government, donor agencies, food industry, local academic institutions, food legislators, and consumers. Adequate monitoring of food fortification is essential and should include both monitoring of critical control points in the production and distribution of fortified food and monitoring of the micronutrient status of target populations, in establishing the need for intervention and to assess the impact of food fortification. The importance of this underlines the need for agreement on suitable clinical and analytical methods to be used; where satisfactory methods do not exist, improved procedures should be developed. Following the deliberations of the consultation, general recommendations for food fortification were agreed upon, and specific recommendations were made with respect to the technical aspects of food fortification as deemed necessary.

General recommendations

The consultation agreed upon the following general recommendations regarding food fortification:

- » Where foodstuffs cannot provide naturally occurring essential nutrients to population groups, the use of fortification, following the principles outlined in the Codex Alimentarius, should be given serious consideration as a means of achieving ICN goals;
- » A multisectoral approach must be adopted in the establishment of any food-fortification programme, encompassing the participation of relevant governmental organizations, food industry, trade organizations, consumers, academic and research facilities, marketing specialists, and any involved international organizations and agencies;
- » Efforts should continue to harmonize national legislation concerning fortified foods with the international standards of the Codex Alimentarius;
- » International guidelines to advise food-aid donors on acceptable and safe fortification practices should be developed; guidelines should not be so restrictive as to impede the provision of high-quality food-aid commodities nor to hinder communication on fortification between relevant parties;
- » There should be appropriate fortification of foods used in food-aid programmes, with donors being required to provide relevant nutritional information, particularly through adequate labelling;
- » Levels of fortification should be evaluated and adjusted according to the bioavailability of the nutrient(s) in the diets of target populations;
- » It is important to evaluate the potential of local food industries to become involved in the production of high-quality fortified food products, including those destined for use in food-aid programmes, in areas where problems of micronutrient deficiency are likely to occur;
- » Food-control systems based on HACCP principles, risk-based inspection procedures, and internationally accepted analytical methods should be developed in support of fortification programmes;
- » The impact of food fortification on the nutritional status of target populations should be monitored so that appropriate corrective action can take place as required.

Recommendations regarding legislation and international standards

The consultation recommended the following:

- » Establishment, at the international level, of an advisory list of nutrients for use in food fortification;
- » Determination of the need for additional regulations, at the national level, pertaining to fortified foods according to specific regional, national, or even local situations;

- » Further consideration of evidence indicating the undesirable effects of excessive intakes of essential micronutrients in order to establish maximum levels of fortification where necessary.

Food legislation

The role of legislation

The primary purposes of food legislation are to protect the health of the consumer, to protect the consumer from fraud, and to ensure the essential quality and wholesomeness of foods. Food law must first provide the legal authority and an adequate legal framework for the food-control activities. It has been found that food law is managed most effectively in two parts: a basic food act and food regulations. The act itself should set out broad principles, whereas the regulations should contain the detailed provisions governing the different categories of products. Within the regulations should be found lists of approved fortificant compounds and food standards stating the allowed levels of nutrients in the fortified foods. This organization gives some flexibility to food laws, as it is much more difficult to have laws amended than to revise regulations. Prompt revision of regulations may become necessary because of new scientific knowledge, changes in new processing technology, or emergencies requiring quick action to protect the public health.

With respect to regulations dealing with fortified foods, changes might be prompted as a result of safety evaluations of nutrient compounds or new information regarding the roles and optimal levels of specific micronutrients in the maintenance of good health. Changes in food-processing and -packaging technologies could be shown to result in a significant reduction in processing and storage losses of micronutrients, thus requiring a revision in the allowed levels of added nutrients. In the face of demonstrated micronutrient deficiencies, regulations regarding standards for certain foods and levels of fortification may need to be revised.

Principles regarding food-fortification legislation

The following principles should be considered in the development of food-fortification legislation:

- » Fortification should always be in the best interests of the selected population;
- » There should be input from interested parties in the development of the law and regulations;
- » The provision of the law should allow flexibility;
- » The law should state clearly what is required or prohibited;
- » The law should create a device for enforcement;
- » The law should provide for quality assurance;

- » The law should provide the government with adequate inspection and sampling powers;
- » The law should contain both incentives and penalties;
- » The law should treat everyone equally and fairly.

Quality assurance and control

Quality assurance and control in food processing

The maintenance of a well-functioning quality assurance programme is essential if a consistent product is to result that meets all required standards. Good manufacturing practices based on the Codex General Principles of Food Hygiene should be established as the basis of any food quality assurance and control programme. In addition, an HACCP system should be developed to ensure that potential hazards are identified and either prevented, eliminated, or reduced to acceptable levels.

A quality assurance programme must consider all activities that have an impact on product safety and quality, from raw materials and ingredients used to product handling, through distribution channels, all the way to the final consumer. Components of a quality-assurance system include:

- » Raw material control: standard specifications must be adopted for all ingredients, which must then be inspected to ensure conformity;
- » Process control: all chemical, physical, and microbiological hazards as well as quality factors must be identified; critical control points must be established and monitored, and a record made of any action taken;
- » Finished product control: this requires that the finished product be unadulterated and properly labelled, and that the integrity of the finished product be protected from the environment.

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Quality assurance in food fortification

All food-production activities must be monitored and controlled within the framework of an effective quality assurance programme. The addition of nutrients to a food for the purpose of fortification increases the number of control points that must be considered. Poor manufacturing control leading to excessively high levels of nutrients in the finished product could have important health implications for the consumer if intake of the nutrient reaches the toxic dose. Conversely, low levels of nutrients in the finished product could render it nutritionally ineffective. This could also have serious health implications if the target population in the fortification programme is at high nutritional risk. Poor manufacturing control could also lead to other quality defects related to interactions of added nutrients with other components of the system.

Conclusions

Food fortification is an important element in nutrition strategies to alleviate micronutrient deficiencies in selected populations. Food fortification must, however, be controlled through the development of appropriate legislation. Adherence to the legislation will ensure that the objectives of the food-fortification programme are achieved and that the levels of micronutrients are controlled within safe and acceptable limits.

The standards, guidelines, and codes of practice adopted by the Codex Alimentarius Commission should be considered in the development of food legislation, including those related to food fortification as they are now recognized under the WTO Agreements on Sanitary and Phytosanitary Measures and on Technical Barriers to Trade.

Key economic issues

Barry M. Popkin

Abstract

Economic issues of fortification that are addressed by economists include the role industry and government should play, the question of compulsory or voluntary fortification, the nature of the economic costs and benefits of food fortification, and the level of public investment justified for implementation and quality assurance. Emphasis is placed on knowledge about the costs and benefits of fortification. Essentially, the literature shows that micronutrient fortification is one of the most cost-effective health interventions and represents a very efficient use of public resources.

Introduction

The perspective taken for this paper is that of an economist called in to work with a country on the design and execution of a micronutrient-fortification programme. In handling this, there are a range of important topics to address that relate to the role government should play, the question of compulsory or voluntary fortification, and the nature of the economic costs and benefits of food fortification. Emphasis will be placed on knowledge about the costs and benefits of fortification. As background, it is surprising how little economic analysis has been conducted. Despite the importance of micronutrient deficiencies in terms of prevalence and impact, there has been surprisingly little systematic research undertaken by economists.

Beginning in the 1970s, there have been several small case studies that have looked at the costs and/or benefits of fortification efforts. In the 1980s there was one large effort by the World Bank and another smaller case study, but now there is an emerging effort to begin to collect cost data in a systematic manner.

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What role should industry and government play?

Generally, governments are expected to initiate fortification efforts that are focused on reaching low-income, high-risk populations in a systematic manner. However, in considering the costs and benefits of such efforts, governments typically focus on the benefits to the nation rather than to the individual or the industry; only when it comes to effects on programme efficiency and impact do they consider the costs to industry and the consumer. In contrast, industry obviously focuses on the impact on its short- and long-term market and profitability. Whereas some companies wish to retain a comparative advantage by having an unequal field where regulations are not carefully laid out, major food companies benefit from clear and precise guidelines. Related to this is a desire not to be forced into adopting fortification that will affect the organoleptic properties (taste, odour, colour) of the product or that will be associated with adverse publicity. The concerns for public education come from the fears of adverse publicity or the need, in a few cases discussed below, to change consumer behaviour to successfully implement a fortification effort.

Compulsory or voluntary fortification?

An excellent short monograph from the World Bank lays out some of the compulsory and voluntary issues in more detail than we will go into here [1]. Voluntary fortification sounds attractive. It does not limit consumer choice and does not force unwilling companies to bear financial costs. In countries where fortification is high on the list of consumer food preferences, e.g., salt and flour in the United States and bread in the Netherlands, voluntary fortification has worked. But in most other countries, consumer demand is lacking, and those companies that act first to fortify take more risks than those that act later or never act. These initial cost components include product development,

market research, and advertising. Competitors adding fortification later often obtain a free ride, or producers may reach only a slim market when they use fortification as a way to increase the market share for their product.

In many cases, those first to fortify get a market advantage, but this is normally true only for products that serve higher-income and educated consumers who are more likely to shift food choice. Lower-income consumers and those in more isolated rural areas are less likely to make such shifts in food choice. Most people experienced in working with fortification feel that compulsory fortification is the only way to proceed to reach the poor. Experience in Latin America has shown us that voluntary fortification or inadequate enforcement of compulsory legislation is associated with poor implementation and reduced benefits of the fortification programme. Even if this situation changes or limits consumer choice, compulsory fortification may be justifiable for a number of public health reasons: widespread prevalence of the deficiency, serious and costly health effects of the deficiency, and cost-effectiveness of prevention versus case management.

Many issues were noted above regarding the assurance of industry cooperation with compulsory fortification efforts. Clearly, food carriers that reach the target population must be identified, and it is desirable that these be centrally processed. Then questions relate to the costs and the price elasticity of this product for the poor. A low cost, which is typical for most fortification efforts, means that the price elasticity for the poor is not a major concern. If the poor reduce their demand when there are small price changes, then it is imperative that costs be kept low.

This is a most complex issue when the fortification process requires an intrusion in the production or marketing process. The most notable examples of this occur when fortification is mandated for products processed in highly decentralized locations or under primitive manufacturing conditions. This has been the case for fortification of salt with iodine in many countries and for fortification of rice in rice-producing Asian countries. Significant costs are added to the process when premixes must be prepared, distributed, and introduced to primitively processed food.

The result is usually a black market selling unfortified salt or rice, incomplete coverage, or both. In a historic attempt to get around these issues, Dr. Chen Junshi lays out most precisely the problems that China faces in attempting to fortify salt with iodine [2].

What are the economic benefits and costs of food fortification?

To begin to gain some sense of the merits of investing scarce public resources in fortification or other micro-

nutrient prevention efforts, one needs to understand the economic benefits and costs of these efforts and then be able to compare these costs and benefits with those of other micronutrient and human resource investments.

Economic benefits

Most public health researchers are aware of the vast literature that reviews most carefully the effects of iron-deficiency anaemia, vitamin A deficiency, and iodine-deficiency disorders on health and behaviour. I briefly summarize this literature, as well as the way an economist might evaluate each of these effects.

The largest and most systematic research has focused on the effects of vitamin A deficiency on morbidity and mortality. A large number of studies have examined most systematically, under varying disease and ecological conditions, the effects of vitamin A deficiency or elimination of vitamin A deficiency on morbidity and mortality patterns [3]. **Table 1** summarizes the results in terms of their effects on mortality rates for pre-school children.

The effects of iron-deficiency anaemia on adult physical performance have been understood for decades, but more recent studies in a number of countries under varying conditions lead us to understand that improvement of haemoglobin status in adult workers, particularly adults in piece work or highly structured production conditions, will enhance economic performance in terms of actual productivity. These studies, conducted mainly among road-construction workers, tea-plantation pickers, rubber-plantation workers, and workers in similar types of occupations, provide a consistent picture indicating that an improved adult haemoglobin status of 1% is associated with a 1% to 2% increase in labour productivity. Levin et al.[4] have reviewed

TABLE 1. Economic costs and benefits of food fortification: Linkage of micronutrient deficiency of vitamin A to improved health and productivity

Relationship	Evidence
Vitamin A deficiency in children ⇒ mortality	85% coverage with supplements or adequately fortified foods leads to reduction of mortality in children 1 to 6 years of age: » 34% in areas of clinical deficiency » 23% in areas of moderate to high prevalence of subclinical deficiency » 10% in areas of marginal to low prevalence of subclinical deficiency

these studies. An earlier World Bank report by Levin [5] examines these studies in more detail.

Levin et al. [4] also reviewed briefly the vast literature on the relationship between iron-deficiency anaemia and iron supplementation as it affects cognitive function and learning or aspects of learning of infants, preschool, and school-age children. Although there are certainly questions regarding some of the conclusions, this literature, which is dominated by the work of Pollitt [6] and his colleagues, Lozoff [7], and Walter [8], provides ample evidence of an important effect of iron-deficiency anaemia and of iron supplementation on recall, concentration, and a few other dimensions of learning and cognitive function.

There is an equally extensive literature that links iodine-deficiency disorders, particularly endemic goitre, to cretinism and reproductive failure. Under severe conditions, stillbirths, spontaneous abortions, and congenital abnormalities occur significantly often. The largest single cause of preventable brain damage and mental retardation is often assumed to be iodine-deficiency disorders.

However, it is probably the more subtle effects of iodine-deficiency disorders on cognitive function that

represent the major cost of this deficiency disease. There are a number of reviews and one meta-analysis on this relationship that come to roughly the same conclusion [9, 10]. There has been less research undertaken on this topic because of the cost and complexity of doing so. However, the historical studies and the more scientifically controlled ones arrive at a similar profile of the effects of iodine deficiency both on the foetus and directly on the infant in compromising cognitive function [11].

Once these health and behavioural impacts are understood, it is necessary to ascertain their economic impact. A summary of the broad set of relationships is presented in table 2. There is a vast literature on methods of evaluating each of these benefits; Levin [5] and an earlier case study in the Philippines present the only attempts to quantify the economic benefits of reducing micronutrient deficiencies [12-14].

Economic costs

In ascertaining the economic costs, it is important to realize that the major rationale for a fortification effort is its long-term sustainability, which can be self-

TABLE 2. Valuation of economic benefits of fortification programmes

Outcome	Benefits	Value
Reduced morbidity	Reduction in health care (depending on patterns of care)	Expenditure on health care, associated travel, and drugs
	Reduction in days of work lost by sufferer or carer (depending on employment status)	Improved marginal productivity of labour
	Improvement in school attendance, concentration, and performance (depending on school enrolment)	Reduction in wasted education expenditure
	Production and consumption benefits	Discounted present value of per capita income over the years of life lost from premature death
Increased physical work capacity	Increased work output (depending on availability of work and complementary factors of production, job type, and skill and intelligence of worker)	Improved marginal productivity of labour
Improved cognitive effects	Greater efficiency of school system; increased future productivity	Reduction in wasted education expenditure Relationship with earnings and marginal productivity of labour

financing. As such, all planning and related efforts are usually focused on ways to front-load the costs that government incurs. These might include foreign exchange for the fortificant or some reduction of taxes and foreign-exchange controls for purchase of the fortificant, preliminary research and planning undertaken by the government, preliminary technical and other research on consumer acceptability financed by the public sector, and social marketing and all quality assurance costs at the retail and consumer level funded by the government. It is typically assumed that costs to the consumer and industry are negligible, and thus they are ignored. Moreover, within-company quality assurance costs are rarely covered by the government.

In a typical situation concerning centrally processed foods, particularly foods handled in ways that are amenable to fortification, such as is found in the baking and milling sectors and the preparation of most condiments, this assumption of minimal costs to industry is typically true. Recent studies on the costs of fortification provide some guide [15]. The most complete review is the exceptional review volume by Lotfi et al. [16]. What these studies and the other cases noted above show is that generally the costs of fortification are very small in terms of annual costs for centrally processed foods. The estimated annual costs per person in 1994 were typically about US\$0.02 to US\$0.20 for iodine, US\$0.06 to US\$0.30 for retinol palmitate, and US\$0.07 to US\$1.07 for iron. These costs vary with the vehicle, the fortificant, the conditions the product will face, and the process used (e.g., premixes). This is a cost per total population reached and gives some sense of the small total cost and the very small likelihood that fortification with a centrally processed nutrient will affect the price of a processed food.

Comparable costs

Alternative measures for eliminating micronutrient deficiencies are typically found to be less cost-effective, particularly in terms of the costs the government faces. Provision of vitamin A and E capsules, iron tablets, or iodized oil injections is typically fully covered by public funds. These costs are typically greater per person than fortification costs. For instance, the studies noted earlier all found that the annual per person costs were US\$1 to US\$3 for injections of iodized oil, US\$0.25 to US\$1.50 for provision of mass dosage capsules of vitamin A plus E, and US\$1.89 to US\$5.30 for provision of iron tablets [1, 4, 12, 15]. Typically, these costs ignore the enormous expenditures in terms of health worker time, transportation, and so forth. They are the marginal costs of the programme.

There are two major ways that these cost relationships can be adversely affected. One relates to the fortification of a food, such as salt, that is processed in a wide-ranging variety of ways, many of which are primi-

tive. This is particularly the problem for salt, as it is processed in many Asian and Latin American countries with large iodine-deficiency disorder problems. When this is the case, provision of fortified salt to be added to crudely processed salt or insistence that salt be centrally processed interferes significantly with the typical salt food chain and leads to unusual costs for the producer and often the consumer. Black marketing and other attempts to bypass the fortification requirements of government regulations are typically the result. Another result essentially places all small primitive processors at risk of losing their means of production.

A second issue is the cost of reaching people at high risk. When this cost is considered, there are many circumstances under which a general approach, such as fortification, turns out to be inefficient. When pregnant women, infants, or pre-schoolers are the target, there are circumstances in which supplementation is more cost-effective when total societal costs are considered. However, when one focuses on costs to the government and ignores the costs industry will bear, there are almost no situations in which fortification is less cost-effective. Moreover, there is absolutely no evidence that supplementation programmes are sustainable over a long period, whereas there is clear evidence of the sustainability of fortification programmes.

There are important gaps in all the cost research to date. None of these efforts have included the costs of quality assurance and social marketing. Quality assurance is particularly important. The steps that specifically require quality assurance are:

- » Purchase quality equipment and supplies;
- » Routinely inspect processing equipment;
- » Validate the mixing process to ensure consistent mixing;
- » Monitor food ready for distribution;
- » Monitor food in the marketplace to ensure that adequate levels of the fortificant are available;
- » Monitor food at the household level to assure that adequate levels of the fortificant are reaching the target population,

The amount of experience and the number of models of quality assurance are insufficient to develop these costs yet.

In addition, it is clear that costs are often underestimated to improve the appearance of programmes. The results are adverse; they can lead to reduced allocation of resources and inefficient programme management. Materials are being developed that provide guidelines for the collection of the costs of fortification programmes [15].

Current experience with cost-effectiveness and cost-benefit analysis

Major efforts in this area have already been noted above [4, 12, 13, 15]. For such an important set of nutritional

problems, this represents a small effort in the analysis of the costs and benefits of eliminating micronutrient deficiencies through fortification. But there is also a vast set of experiences by the food industry, particularly flour and other cereal processors and manufacturers using cereal-based products. There is also ex-

tensive experience in other manufacturing sectors.

At this point, the major gap appears to be application of economic analysis to actual large-scale fortification efforts. However, there is only the experience of attempting to estimate costs for the Guatemalan sugar fortification effort by Phillips et al. [15].

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Forging partnerships among industry, government, and academic institutions for food fortification

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Abstract

This decade commenced with a declaration by the heads of state attending the World Summit for Children that they would pursue the virtual elimination of iodine and vitamin A deficiencies and reduce iron deficiency by 33% before the year 2000. The World Bank has estimated that the economic, socio-economic, and health benefits of sustained elimination could contribute as much as 5% of gross domestic product annually to an affected country for an investment of less than 0.3% of gross domestic product. By 1996, tremendous progress towards the elimination of iodine deficiency had been made, largely due to the involvement of the private food industry in the production and distribution of iodized salt. For goals in preventing vitamin A and iron deficiencies to be achieved, a similar commitment on the part of the food industry is necessary. In 1995 we conducted a survey of 95 representatives of multinational and national food companies and 68 representatives of government and international agencies about private-public partnerships to eliminate micronutrient malnutrition. The survey showed a lack of communication from the public sector to the private sector, although both sides suggest that such communication would be effective and desirable. An international dialogue entitled "Sharing Risk and Reward: Public-Private Collaboration to Eliminate Micronutrient Malnutrition" was held in Ottawa in December 1995, where a framework for communication was established. From this foundation, many countries have initiated or reopened dialogues among governments, industry, agencies, academia, and civic organizations to support the elimination of micronutrient malnutrition.

Background

The physical deformities of goitre, cretinism, and blind-

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ness resulting from micronutrient deficiencies have been evident in populations through the ages. Mayan pottery and Chinese carvings bear witness to the more visible toll of micronutrient malnutrition [1]. The correction of these deficiencies through food fortification began with salt iodization in the United States and Switzerland in the 1920s. In the 1930s and 1940s, iron was added to cereal flour to reduce losses due to milling. Food fortification continues to be a widely used mechanism in many industrialized countries due to rapidly changing lifestyles and increasing reliance on more highly processed foods to provide nutrients lacking in the normal diet of the population. Urbanization and the relatively high costs of fresh meat, fruit, and vegetables are used to justify the addition of nutrients to a range of low-cost or subsidized foods to ensure that the dietary intake of micronutrients is adequate [2].

It is important to note that there is no consensus regarding the extent to which food should be fortified, and the prevailing attitude towards it varies in countries of the industrialized world. Europe has restrictive legislation regarding the addition of micronutrients to foods. Such restrictions have again put populations at risk of iodine deficiency even in the 1990s [3]. In North America food fortification is viewed more positively. However, the use of iodine compounds to sterilize milking machines contributes to the protection of the population from iodine deficiency. Iodine intake in the United States has also been enhanced by adding iodine to the bread-making process, such that iodine has been available adventitiously rather than through planned public health intervention [4]. It is clear, however, that the elimination of micronutrient deficiencies from these countries has been attributed in large part to food fortification. Food scientists have risen to the challenges posed by micronutrient fortification. Evidence of their success is clearly shown on the supermarket shelves in most developed countries. Technical problems have been overcome for an ever-widening range of applications. These barriers include the interaction of added nutrients with the food carrier matrix due to the pro-oxidant and catalytic properties of many essential minerals and

the susceptibility of vitamins to destruction by heat, light, and oxygen [2].

Key issues

At the National Advocacy Meeting to End Hidden Hunger in 1993, President Ramos said, "I reaffirm our country's commitment to the 1990 World Summit for Children to end malnutrition, preventable disease, and illiteracy. I likewise reaffirm the Philippine delegation's support for the Montreal Conference of just a few years ago on ending hidden hunger before the turn of the century." At the same meeting, then Secretary of Health and now Senator Juan Flavio Velasco said, "To the country, every individual saved from hidden hunger is an added resource—one more pair of strong arms to build and produce, one more good pair of eyes to find solutions to the nation's problems, one more intelligent brain to plan the course of development." More than 123 other nations around the world have made similar commitments. These commitments were supported by corresponding resolutions at the FAO/WHO International Conference on Nutrition (ICN). International agencies, including UNICEF, the United Nations Development Programme (UNDP), and the World Bank, committed support to these goals. Government development agencies, including those of Canada, the United States, Australia, and the Netherlands, to name a few, reaffirmed their support for these goals and made substantial commitments towards their achievement.

In 1994 the World Bank issued the following statement: "The control of vitamin and mineral deficiencies is one of the most extraordinary development-related scientific advances of recent years. Probably no other technology available today offers as large an opportunity to improve lives and accelerate development at such low cost and in such a short time. Deficiencies of just vitamin A, iodine, and iron could waste as much as 5% of gross domestic product, but addressing them comprehensively and sustainably would cost less than 0.3% of gross domestic product [5]."

We are approaching the closing of this decade, dedicated to achieving the goals of the World Summit for Children. Progress has been made; 70% of the world's salt is now iodized and available in households [5]. Such success shows what can be done when governments, agencies, and private companies cooperate. However, serious gaps remain. Much of the salt labelled as iodinated has either too little or too much iodine. There is a lack of comprehensive quality assurance programmes, infrastructure, and financial systems to maintain salt iodization. In the countries of the former Soviet Union, the relationship of iodine deficiency to post-Chernobyl thyroid cancer is only now being recognized, and iodine deficiency is not being adequately addressed. Efforts have been made to reduce vitamin A deficiency

through capsule-distribution programmes, which only a handful of countries perform to scale. Gardening programmes have not had an impact on vitamin A deficiency. As resources diminish in the public-sector and donor communities, these programmes are in jeopardy of being cut. Little progress has been made to eliminate iron deficiency, the most widespread and economically debilitating of the three deficiencies. In the Philippines alone, it is estimated that more than half of children and mothers are anaemic because of iron deficiency [6, 7].

An assessment of the situation calls for new approaches and a new set of partners to deal with this issue. There are many compelling reasons to look to a private-public partnership to help with the resolution of this problem. There is a power and financial shift away from big government taking action and responsibility for the entire population [8]. The trend is towards devolution of responsibility and resources from centralized to constituent administrative levels and towards reduction in national government spending. International donor resources are diminishing and are becoming less available to promote home gardening and capsule distribution or to purchase and maintain fortification units. Clearly, the development agencies do not have either the resources or the persistent staying power to see the full resolution of this problem. They struggle to reinvent themselves as they look at new issues that become the focus of their attention. The agencies often concentrate on approaches that will demonstrate dramatic results in a short time. There is a trend to incorporate these focused activities within a wide array of other developmental issues, rather than to be called upon to account for these specific commitments.

The problems of micronutrient deficiency affect a much larger proportion of the population than those who have evident clinical symptoms. When more sensitive biological sample testing is applied to populations, it is evident that newborns and mothers are affected in large urban centres as well as in rural settings. This makes it rational to target micronutrient supplementation not only to poor subsistence farmers but also to a much wider population. Fortification cannot reach all people with deficiencies of essential micronutrients, especially those with restricted access to centrally processed foods because of geographic remoteness, poverty, or cultural preferences. But for the bulk of the population, fortification can make a crucial difference. Across geographic, social, and economic lines, consumption of foods fortified with micronutrients can unlock the enormous human and economic benefits suggested by economists and nutritionists. Defined populations beyond the reach of fortified products can be targeted with specific interventions, such as capsule distribution or other food-based programmes.

Another reason for private-public partnerships re-

lates to the fact that neither government nor agencies have the expertise or capacity to produce or distribute food in mass quantities. Because of limited bioavailability, dietary modification may not be as effective as once believed. Furthermore, food fortification is affordable, immediately cost-effective, safe, self-financing, and sustainable, and provides high coverage [9].

“Lend us your expertise. Share with us some of your resources. This is the imperative of good corporate citizenship—a concept that I am happy to say is alive but not yet too strong in our country.” These were the words of President Ramos during his closing remarks at the National Anti-Poverty Summit on 21 March 1996, directed to the country’s business community and asking them to actively support and participate in the government’s effort to fight poverty. Private and public initiatives working together for the benefit of people have become the new catch cry for development of the 1990s. No other issue is better suited to such partnerships as the elimination of micronutrient malnutrition through food fortification, yet this is no simple matter. We are faced with a wide array of barriers, including a lack of trust, a lack of communication, and a different set of objectives, approaches, and realities to relate to. One thing is clear: the voter, the target population, and the consumers are the same people who stand to gain or lose the most, depending upon the success of this partnership.

A survey

In preparation for the meeting “Sharing Risk and Reward: Public-Private Collaboration to Eliminate Micronutrient Malnutrition,” held in Ottawa in 1995, more than 200 private executives and public officials were asked about their experiences with food fortification and with each other [10]. Ninety-five executives of private food companies and 68 public officials responded to the survey. Survey responses were summarized and categorized into 26 issues; the number of times each category appeared in a survey response was totalled. This is not a representative sample and not a strictly scientific analysis. We simply looked for recurring messages and trends that might suggest useful topics for discussion between representatives of the public and private sectors. The results are summarized in figures 1 and 2.

Both public- and private-sector respondents painted a picture of a communications gap between the food business and governmental, non-governmental, and international agencies. Half the private sector reported no contact from public officials about micronutrient malnutrition issues or how they might be part of the solution. Only about 60% of the public sector reported communicating with the private sector about goals to eliminate vitamin A, iron, and iodine deficiencies.

This communications gap confirmed the need for

exchange. However, the survey also showed that there is plenty of opportunity. When the public sector did communicate, it was often perceived as effective communication. Eighty percent of the managers who received communication from the public sector reported that it was effective. Similarly, 93% of the public-sector officials reported a positive response to their communication efforts. Moreover, private-sector respondents seemed overwhelmingly interested in regular contact with governments and international agencies about micronutrient malnutrition issues. Eighty-seven percent said they would be interested in regular communications with the public sector and that those communications would have an impact on their business decisions. Eighty-one percent suggested that they would be receptive to collaboration with the public sector, including the sharing of technology and marketing information. Beyond defining a need to talk and suggesting an openness to collaboration, the survey provided a strategic focus on the issues. We asked both public-

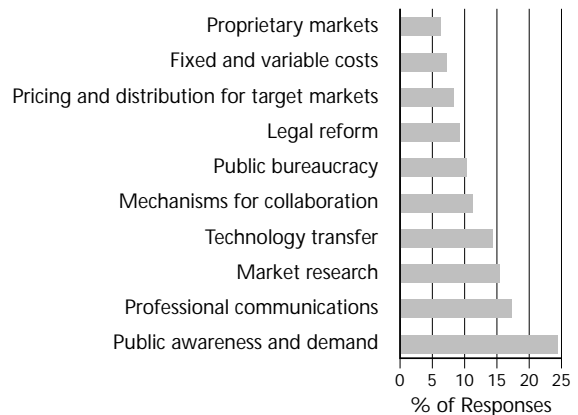


FIG. 1. Private priorities



FIG. 2. Public priorities

and private-sector respondents to “outline the issues for a dialogue on private–public sector collaboration to stimulate the production and marketing of micro-nutrient-rich foods” (figs. 1 and 2). A look at the top 10 issues raised in response to this question shows where issues and priorities match and where they diverge.

For the purposes of a dialogue between the public and private sector, we might divide these contrasting lists of priorities into three general groupings. First, where there already is a general agreement on priorities between public- and private-sector responses, public and private sectors might begin to work on concrete strategies and action plans. Next, where there are diverging perceptions on priority issues, we can listen and learn from each other. Finally, on issues where public and private goals diverge, we are left to recognize that there are limits to our ability to collaborate, and we need to agree not to let our differences prevent us from working together.

Clustered at the top of both lists—reflecting both the frequencies with which the issue was raised and the relative matches between public- and private-sector priorities—is a shared concern for *raising public awareness and creating consumer demand*. Equally strong in terms of shared concern and agreement between public and private respondents is the area of improving *professional communications*. This category includes all survey responses dealing with improving the flow of scientific, nutritional, technical, and marketing information about micronutrient malnutrition in general and fortification in particular. The flip side to this positive agreement on the need for professional communications is a shared concern about the lack of *mechanisms for collaboration*. Our survey responses show that there is awareness of the lack of established rules of engagement between public and private sectors and that our individual roles need to be defined, clarified, and validated. Through a dialogue of public and private sectors, these areas of a consensus can be expanded to include a notion of shared responsibility. This suggests the potential for an action-oriented focus on establishing partnerships for joint education and awareness activities, initiating clear channels of public–private communication, developing professional relationships, and building organizational linkages.

Other issue categories show diverging perceptions of public and private sectors. Our list of 10 priority issues for discussion splits when we come to *market research*, which is tenth on the public-sector list and third on the private-sector list. This category includes references in survey responses to market research, market sizing, consumer profiles, and epidemiology, the traditional market-research tool of public health. Epidemiology works to define the source and extent of the problem and then measure the effectiveness of specific solutions. As a result, social marketing, a rather new activity within the field of public health, tends to tar-

get and promote pre-existing solutions. On the other hand, the food industry, with a longer history of marketing, looks to a fuller marketing mix of product development, pricing, and packaging as well as promotion. One might say that for the private sector, marketing and market research are actually part of developing the solution and not just a way to deliver it.

This different perspective on the role of marketing and market research might help explain why *long-term growth opportunity* is a public-sector priority for discussion but is not included in the private-sector list of priorities. Does this really reflect a differing view of the potential long-term opportunities for fortified food products? Or might it simply reflect the reluctance of business to take risks and judge opportunities without first seeing the market research? Perhaps this divergence in priorities simply reflects a public-sector focus on the size of the need as opposed to a private-sector focus on the size of the opportunity. Perhaps there is more agreement here than the divergence in the public- and private-sector lists of priorities indicates.

Within public institutions and private companies, there is a wealth of resources, data, and personnel upon which good market research can be built. Once we begin to understand each other’s approach to market research, we might begin to address ways we can collaborate not simply on the promotional aspects of raising public awareness and demand (where we already agree), but on developing new and innovative products and solutions. Market research might become a tool for our collaboration—a tool to translate the public-sector focus on the size of the need into the private-sector emphasis on the size of the opportunity.

The survey shows that public officials put more emphasis on economic barriers to fortification. Higher *fixed and variable costs*, in turn, have an impact on *pricing and distribution for target markets* (in other words, low-income consumers). Both categories were raised more often by public- than private-sector respondents. In fact, throughout the survey, public-sector respondents seemed to take a more negative view of the economic environment for fortification than did the private sector. When asked if there were economic constraints on fortification, 75% of the public-sector respondents said that there were. On the other hand, when we asked the private-sector respondents whether they had experienced economic benefits from fortification activities, about half said they had. Likewise, when asked about constraints, about half said there were none. Overall, this represents a balanced feel for the benefits and constraints, as opposed to what seems to be a greater perception of constraints on the part of public-sector respondents.

This split in perception is possibly related to the public-sector focus on and responsibility for the welfare of the “poorest of the poor,” in contrast to the private sector’s freedom to carve out niche markets of oppor-

tunity. Might a dialogue work to align these contrasting points of view? It is possible that public-private collaboration in market research has the potential to define new products, new pricing, and new distribution mechanisms that could create new niches of opportunity for food products among low-income consumers. Public-private collaboration can focus on the development of what we might call a *public health market*. It may simply be a matter of beginning our collaborative efforts early on in the market research process as well as a focus on developing solutions rather than on the production and promotion of pre-existing products.

Finally, there are areas in which public and private goals and cultures diverge in some very basic ways. Ranking of contrasting public- and private-sector priorities for discussion brings into relief varying views on legislation and regulation. The issue of *legal reform* is a lower priority for the private than for the public sector, and the issue of *enforcement of regulations and quality assurance* does not appear on our list of private-sector priorities. It is a reflection of differing organizational goals, cultures, and operational values. For example, in answering the question "What factors prompted your organization to implement food-related regulations, standards, or other codes of conduct," public health-sector respondents pointed out issues of health, safety, quality assurance, and social responsibility. The private consensus seems to be that public policy should provide an environment in which private companies can compete, innovate, and develop a growing market for fortified food products. It is interesting that not one of the public-sector respondents suggested that a reason to regulate was to provide a business environment for food companies conducive to the development and marketing of fortified food products. On the other hand, *benefits to the national health* are only listed as a public-sector priority for discussion.

Our survey indicated that one of the private sector's top priorities for discussion is *public bureaucracy*—a lack of orientation to results, clarity of goals, decisiveness, and follow-up. These negative comments by the public-sector respondents were an undercurrent throughout the survey. Much of it had to do with the perception that the public sector wanted to place limitations on which foods are appropriate to fortify and which consumer groups are appropriate to target. However, about two-thirds of our public-sector respondents felt the field was wide open with respect to foods, and almost 80% felt that all consumers should have access to these products. Furthermore, the survey responses indicated that the public sector seems to be aware of its own limitations. When responding to a question on barriers to fortification, one-third of our public-sector respondents commented on politics, bureaucracy, and legal issues as barriers. Likewise, many private-sector respondents expressed an awareness of their own limi-

tations, commenting that the rigours of profit-making enterprises and the stress on short-term return often restrict involvement in what they consider to be some worthwhile social enterprises. Our surveys seem to show that both public and private sectors are aware of their own professional limitations when it comes to a collaboration on addressing the issue of micronutrient malnutrition. Through dialogue, perhaps we can come to an understanding and awareness of each other's limitations.

Both the public and private sectors have a role to play in the global elimination of micronutrient malnutrition. A dialogue between the sectors needs to translate the needs of more than 2,000 million people who do not get enough vitamin A, iron, or iodine in their diets into professional opportunities for action and collaboration. As we jointly take the risks involved in collaboration, we can all look forward to the promise of sharing in a truly great reward.

Opportunities arising from an international dialogue

The Micronutrient Initiative, the Program Against Micronutrient Malnutrition, and the Keystone Centre, with the additional assistance of the US Agency for International Development, the International Life Sciences Institute, and the World Bank, invited a diverse group of interested persons to Ottawa on 6-8 December 1995 [10]. The Ottawa Forum on Food Fortification was convened recognizing that although micronutrient malnutrition is a global problem, it will be eliminated one country at a time. We started with the realization that governments and the food industry had already been working together in a number of countries, providing a rich experience from which to learn. The published proceedings of this unique and energizing meeting have already provided a springboard for collaborative action to enhance micronutrient malnutrition in a number of countries [10]. A smaller global follow-up meeting, "Partnerships to End Hidden Hunger: Meeting to Get Concrete," was held in Atlanta on 15 November 1996. Some of the following key ideas emerged from these meetings.

Need for market-based solutions

Whereas capsules, injections, and nutrition education to improve micronutrient status are primarily delivered to vulnerable populations through a network of public health, welfare, and education services, fortified food products are primarily delivered to consumers through private production and distribution. Market-based and consumer-driven solutions, historically developed by the private sector, should be explored. However, in most countries, channels of communication

and mechanisms for collaboration between public and private sectors have not been developed. Addressing micronutrient malnutrition through a market-based food-fortification strategy entails developing a new paradigm of public-private collaboration and communication. Following an appropriate situational analysis, a first step in this process may include a national dialogue between the public and private sectors and establishment of national and sub-national partnership round tables.

A call for leadership: Communications and marketing

Low consumer awareness of micronutrient malnutrition and lack of demand for fortified food products are major barriers to investment in the elimination of vitamin A and iron deficiencies. A major obstacle to overcoming insufficient awareness and demand is a lack of communication and coordination among the various professional sectors that have the resources and the credibility to serve as public advocates and educators. The public health community works to define the extent and impact of micronutrient malnutrition. Pharmaceutical companies research the production of micronutrients. Food companies develop the technology of fortification. Nutritionists and market researchers study local consumption patterns. The media publish and broadcast on health and development issues. Input from these and other sectors is needed to develop effective marketing strategies and messages. Unfortunately, there is little communication among them.

Each professional community has its own distinct language, goals, and audiences. Consequently, the range of messages is specialized and fragmented, and tends to confuse the consumer. In some cases, the message is wrong. For example, scientifically framed information, like the often-heard call for a reduction in infant mortality, does not resonate with a mother shopping for milk or flour. In other cases, the messenger is inappropriate. A message from government public health "authorities" does not have the credibility of a personal endorsement by a family physician. Unfortunately, family doctors are often uninformed about micronutrient issues. Some participants felt that getting the right message delivered by the right messenger to the right audience entails a new kind of leadership to pull together the efforts of the various professional communities.

There was some discussion of an international communications strategy. Some questioned the appropriateness of this approach, since action to eliminate micronutrient malnutrition unfolds on a national stage. Most participants agreed that national communications approaches need to integrate professional and technical constituencies in advocacy to governments and marketing to consumers. However, many felt that communication to professionals and policy makers in government, medicine, business, and research is increas-

ingly via global media, international trade, and professional associations. Both national and international channels need to be cultivated. There was some suggestion that messages to the consumer could wait on marketing to a range of professional public- and private-sector organizations. These, in turn, can serve as effective and credible messengers to the general public.

Several participants expressed interest in developing these concepts to the next stage. The implementation of "umbrella" public relations and marketing activities may parallel efforts of professional and trade associations in which a range of diverse interests jointly invest in "growing the market."

Collaborating to create an enabling environment

In most industrialized nations, micronutrient deficiencies have been eliminated through a joint public and private effort that created an enabling environment for the development of a range of fortified foods. However, in many countries where micronutrient malnutrition remains a public health scourge, a range of constraints frustrates such an environment: bias against food additives, low professional awareness, limited consumer demand and purchasing power, arbitrarily enforced regulations, and other government economic policies and programmes. Even though the need for micronutrients is clear and potential markets for fortified products are large, these negative market factors inhibit investment, and private capital is drawn to a range of competing opportunities. A public-private collaboration can more attractively position fortified food products in relation to competing investment options. A partnership of governments, development agencies, national and multinational companies, and a range of scientific, professional, trade, civic, and volunteer organizations can reduce the perceived risk and increase the potential return of investments in fortified foods by collaborating to raise awareness, create demand, transfer technology, and engage in a variety of joint ventures in product development, production, distribution, and marketing.

A stake for multinational companies in a national collaboration

In many nations where micronutrient malnutrition remains a significant public health concern, rapid urbanization, changing consumer preferences, and rising incomes offer opportunities for investment by multinational companies. Collaboration to expand the consumption of fortified foods in these nations offers a vehicle to forge alliances with national governments which define the investment climate, identify strategic alignments with national companies, and create a positive image among consumers. Moreover, the elimination of micronutrient malnutrition in developing coun-

tries will have a significant effect on the productivity of workers and the purchasing power of consumers. Many multinational food companies are based in North American and European nations, which are signatories to the World Summit for Children and the governments of which are investing in the elimination of micronutrient malnutrition. Participation in collaborations to eliminate micronutrient malnutrition abroad can have a positive impact on corporate relationships with these governments as well as with consumers in industrialized nations.

At the present time, value-added products produced and marketed by many multinational food companies are not always consumed by those most at risk of micronutrient malnutrition. However, there is evidence that fortified value-added products stimulate interest among professionals and consumers alike, thereby achieving the critical mass of political support and consumer awareness necessary for broad-based fortification of staple foods. Although currently beyond their reach, these value-added products speak to the aspirations of consumers. As producers of value-added products, multinationals are major customers of commodity products and, therefore, have influence on producers of staple foods. Moreover, many national companies look to multinationals for expertise in fortification technology and in marketing fortified products. Thus, the presence of multinationals can create opportunities for technology transfer through licensing and other partnership arrangements. In this unique position of influence with both producers and consumers, multinational companies are poised to catalyse national dialogues to eliminate micronutrient malnutrition. To date, there has been no concerted effort to define a special role for or to enlist the support of multinational food companies in national programmes to eliminate micronutrient malnutrition.

Good corporate citizens

It is clear that corporations thrive by solving consumer needs with consumer products and not necessarily by directly addressing social concerns. In some cases, a company will find an opportunity to profit from a product that also happens to provide health benefits. In other cases, contributing to social goals improves their image with the consumers who buy the product and their access to policy makers who play a large role in determining the business environment. Public-private collaboration to eliminate micronutrient malnutrition involves both of these scenarios.

Most participants agreed that multinational corporations and some national companies could provide access to fortification and other food-processing technology. It is acknowledged that public domain technology can be shared through publication in peer-reviewed professional journals and trade journals.

Information about proprietary technology can be disseminated through newsletters, CD-ROMs, and the Internet. Although some have questioned the impact of value-added products and sophisticated technology on poor populations in developing nations, others have suggested that currently available products and technologies could have a significant impact on micronutrient malnutrition. In some cases, fortified "sachet" products have been developed and are waiting for market opportunities. In other cases, "the nutritional guts" of more expensive products can be adapted to fortifying staple foods.

There was general agreement that corporate technologists could make a major contribution to training both public- and private-sector personnel. Public-sector participants noted that national governments and food companies need assistance in a range of areas, including process technology, packaging, and market research. Private-sector participants responded that under the right circumstances, this kind of service could be forthcoming.

The group recognized that several factors constrain these kinds of contributions. A lack of workable international standards and inconsistent national standards inhibit the ability and motivation of companies to transfer their knowledge, expertise, and experience. Corporate participants suggested that costs are driven up and investment opportunities are passed over because corporations face ambiguous legislation, unclear regulation, and arbitrary enforcement. Although corporate participants indicated a willingness to assist in tackling issues involved in fortifying foods for less advantaged populations, in many countries vague and conflicting public policy makes fortifying foods a risky venture, even for the more affluent markets. A tested method of arriving at consensus standards may be through an international dialogue involving both public and private parties.

Participants expressed interest in advocating to the Codex Alimentarius the development of clear guidelines, particularly on fortification of foods with iron. All agreed that Codex guidelines would work to motivate and ease the way for national governments to adopt clear and consistent policies to enhance the investment environment for food fortification. It was noted that working with the Codex is a slow process, but that a Codex Working Group on Fortification was recently established. With international goals to eliminate micronutrient malnutrition by the year 2000 ratified by 123 heads of state, there is a window of opportunity for an alliance of public agencies, academic and research institutions, and private companies to advocate a sense of urgency to the Codex Commission.

Undeveloped channels of communication are another factor inhibiting greater participation by companies in programmes to eliminate micronutrient malnutrition. Communicating information about public domain

patents or favourable terms for licensing proprietary technology requires a neutral and secure third party to serve as a broker. Bringing corporate expertise to bear on national market research entails a third party that understands the needs of country programmes and the strategic interests of multinationals, and can help make a match.

Participants reported that there is no clearinghouse supplying information necessary to connect companies, expertise, and resources to private companies and public agencies that might benefit. It was noted that on a regional basis, UNICEF Central America is about to undertake an inventory of fortification activities. On an industry basis, the International Sugar Organization is developing a role as an information clearinghouse for fortification of sugar with vitamin A. These models might be replicated by other industry trade groups, such as the International Life Sciences Institute, International Grain Council, and Association of Oil Chemists, or on a regional basis by organizations such as MERCOSUR, the Asian Pacific Economic Council (APEC), or regional UNICEF offices.

Measuring the benefit

There is a need for clear and persuasive micronutrient assessment data at all stages of elimination programmes. Clear data are crucial to convincing governments that there is a micronutrient problem and that fortification efforts should be supported. Pilot projects or clinical trials need credible data to assure both regulatory authorities and private investors that a particular fortified product does make a difference to micronutrient status. If smaller fortification efforts are to be replicated or developed on a larger scale, data are needed to confirm that those current efforts are, in fact, effective. Finally, clear assessments are needed to monitor the progress of national-scale programmes.

Participants pointed out that although the private sector has established laboratories to measure the content of nutrients in *food*, public health laboratories, such as those at academic institutions, and government-supported centres of excellence, need to extend to measuring micronutrient levels in *populations*. There was a call for developing cooperative relationships among public and private technical and laboratory capacities to provide this crucial resource for advocacy, product development, and evaluation.

It is clear that current methods for micronutrient status assessment for vitamin A and iron deficiency have significant limitations for application in developing countries. Dietary assessment of vitamin A status provides a description of intake patterns but gives no reliable quantitative indication of the actual level of deficiency. Clinical assessment methods are ineffective in evaluating moderate and mild levels of deficiency. Biochemical measures provide a more quantitative assess-

ment of micronutrient status but are limited by the complexity and cost of sample collection, transport, and analysis. A need exists to develop and field test a core set of indicators of vitamin A status that can provide a reliable, practical, and affordable basis for community assessment, monitoring, and programme evaluation. Similarly, rugged and reliable methods for iron status and folate status indicators need to be developed.

Harnessing the power of the grass roots

Civic organizations, such as the Red Cross in Thailand, the Kiwanis for the elimination of iodine deficiency globally, and Sister Cities International (SCI) with their SCI/Program Against Micronutrient Malnutrition (PAMM) Hidden Hunger Initiative, are important allies in any global or national partnership. They offer lines of communication with civic authorities as well as a range of community leaders and volunteers down to the grass-roots level. These organizations are often in an ideal position to facilitate municipal nutrition assessments to gather data about levels of micronutrient deficiency in specific cities. Or they might work as consumer groups to assist regulatory authorities to ensure that fortified food products meet standards of quality. Working together, local government and business leaders might develop a range of approaches to enhance investment in the production and consumption of micronutrient-rich foods. One participant noted that even though many regulatory and other barriers to fortification of foods exist on a federal level, a grass-roots municipal constituency can be a powerful advocate for policy changes at the national level.

It is clear that fortification efforts are enhanced when government agencies, large corporations, and civic organizations coalesce into a web of opportunity through which employees, customers, and their families can have an impact on programmes and policies.

Barriers to overcome and future action

Although public officials and private executives generally endorse the concept of public-private collaboration to eliminate micronutrient malnutrition, they are unaware of channels of communication or mechanisms that might allow collaboration to move forward. They will meet barriers that will include the following issues. The nutrition community, agencies, governments, and non-governmental organizations sometimes feel a sense of ownership of the micronutrient problem and are reluctant to share roles and responsibilities with others. Some nutrition and public health advocates have an inherent distrust of the private, commercial world, especially large companies. The battle over breastfeeding versus breastmilk substitutes has created passionate groups that perceive either the public health commu-

nity or the private food industry as the enemy. There is concern by the public sector that fortification choices may not cover the most needy populations but may result merely in profit taking with inappropriate foods, which they consider a distortion of diets. The food industry is concerned that when dealing with governments and agencies, they will be caught in a bureaucratic process that will absorb their time and resources.

The elimination of micronutrient malnutrition will

be made possible by broadening the support base for what will certainly be a landmark achievement. By working together, we can play a role in assisting national governments and industries to reduce the incidence of micronutrient malnutrition while reducing the risk of investments in fortified foods. We look forward to a fruitful collaboration with a variety of partners, so that we all may see a twenty-first century free of micronutrient malnutrition.

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Fortification of sugar with vitamin A

Oscar Pineda

Abstract

The technology for fortifying sugar with vitamin A was developed in Guatemala in the mid-1970s, and the Guatemalan government enacted legislation to make fortification mandatory in June 1974. This action was copied by other Central American governments. The fortification programme in Guatemala developed in two stages. In the first (1975-77), the fortification programme was evaluated four times at six-month intervals and was shown to be effective. The sugar industry was responsible for carrying out the programme, but the programme was suspended, mainly because of economic arguments. After 10 years of effort, the programme was restarted in 1989. At this time the programme was combined with an initial mass distribution of vitamin A capsules to pre-school children, which began the first successful social mobilization effort in the area. The programme was evaluated for six months and was shown to be effective in improving the vitamin A status of the Guatemalan population. This second stage has been active continuously since 1989. With improvements in the technology of fortification, new approaches have been tested, and now it is possible to obtain an excellent sugar doubly fortified with vitamin A and iron, using new iron products of high bioavailability that do not alter the organoleptic characteristics of the sugar and do not produce unwanted colour changes during processing. To avoid the rancidity of premixes, new processes of dry mixing have been developed in which no oil is used. This opens a real possibility for the fortification of sugar with other nutrients. Sugar fortified with vitamin A, iron, and zinc, either alone or in any combination, is commercially available in Brazil, where, under the guidance of the Latin American Centre of Nutrition and Metabolic Studies (CELANEM), the procedures have been developed using iron amino acid chelated minerals.

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Mention of the names of firms and commercial products does not imply endorsement by the United Nations University.

Introduction

Vitamin A deficiency continues to be highly prevalent in developing countries. The World Health Organization (WHO) estimates that in at least 75 countries, the deficiency is a problem of public health importance [1]. Of the many approaches that have been taken thus far to control vitamin A deficiency, sugar fortification seems to be the most cost-effective method [2]. According to a UNICEF report on sugar fortification in Guatemala, the cost of fortification is about one-fifth of that of other interventions [3]. Because of the success of the sugar-fortification programme in Guatemala that was carried out for two years in the mid-1970s and initiated again and maintained since 1988, this approach has become the preferred intervention in those countries where it is feasible.

To bolster the potential of sugar-fortification interventions, UNICEF obtained a resolution from the Council of the International Sugar Organization during its meeting in São Paulo, Brazil, in May-June 1995. The resolution stated that the council agreed to facilitate fortification programmes in those countries where governments were considering such interventions.

In most countries, sugar fulfils the criteria listed by the Council of Food and Nutrition of the National Academy of Sciences of the United States as a good vehicle for fortification with specific nutrients [4, 5]:

- » The food used to supply the nutrient should be consumed in significant amounts by essentially all members of the targeted groups of the population;
- » The addition of the nutrient will not cause any imbalance of essential nutrients;
- » The nutrient is stable in the vehicle under normal conditions of storage and use;
- » There is reasonable assurance that no excess intake will be induced.

For programmes of fortification in developing countries, some additional factors have to be considered:

- » The food vehicle should be consumed by practically all the population;
- » The daily intake of the carrier food should be es-

sentially constant;

- » Fortification should not alter the organoleptic characteristics of the vehicle;
- » Production and processing of the food vehicle should be centralized;
- » The cost of the fortification should be economical.

In most countries, sugar is widely consumed by the population in quantities that show little daily variation, thus facilitating decisions about fortification levels. The retail price range of sugar generally places it within reach of the lower socio-economic end of a given population, and in most countries sugar production is centralized, which permits easier control and regulation of the fortification process.

To initiate a programme of fortification of sugar with vitamin A, it is necessary to know with enough precision the levels of daily consumption of sugar by the population at large as well as by pre-school children. In Guatemala these values were 36 g/day for adults and 20 g/day for rural pre-school children.

Since there is no single level of fortification appropriate for every country, the rationales put forth in Guatemala as to the level of fortification to be used may aid other countries in which sugar fortification is being considered. These rationales were [6]:

- » To add to the mean daily intake of sugar of the population the amount of vitamin A recommended by WHO for adult daily consumption. In principle, this level is considered high, since even the less privileged groups consume at least a fraction of their daily requirement for vitamin A;
- » To add to the mean daily intake of sugar of the rural population a quantity of vitamin A that corrects the mean daily deficit in their dietary intake and raises it to the recommended amount;
- » To add to the mean daily intake of sugar of rural pre-school-age children the mean safe level of intake for this age group based on the recommendation published by the Food and Agriculture Organization (FAO)/WHO.

Since the information derived from nutrition and dietary surveys indicated that the age group at the greatest risk of deficiency was pre-school children, the last rationale was adopted, which resulted in a level of fortification of 15 µg of retinol per gram of sugar (50 IU per gram). This level has been used in Guatemala since 1986. A similar approach could be considered as a guideline in establishing fortification levels in other countries.

Fortification procedure

After a number of studies, the vitamin A selected for fortification was retinyl palmitate 250 CWS (cold water soluble). This product, a gelatin microencapsulated preparation that contains 250,000 IU of vitamin A per gram and is water-miscible, is manufactured by

Hoffman-La Roche in Basel, Switzerland, and BASF in Ludwigshafen, Germany. The fortification of a sugar premix is carried out in two steps. First, a concentrated premix is prepared containing, in addition to vitamin A, an unsaturated oil as a binder and an antioxidant to prevent peroxidation of the oil. The concentration of vitamin A in the premix is 1,000 times that of the final fortified sugar, which must be diluted with more sugar up to 1,000-fold. The premix is formulated to contain a 10% excess of vitamin A to correct for possible losses during the process. Then, the premix is diluted with sugar to attain the proper concentration of vitamin A. The original premix used in Guatemala had the composition shown in table 1.

To facilitate the preparation of the premix, a special mixer was designed to incorporate in the chassis the mixer, an oil depot with a heater, and a nitrogen bubbler. The horizontal axis of the mixer is hollow to allow the oil in the depot to be added directly to the mixer through sprayers. The principal section of the machine is a Y mixer with charging and discharging gates that rotates on a horizontal axis supported by ball bearings. The horizontal axis that goes through the mixer rotates in the opposite direction to the mixer itself in order to facilitate the addition of the antioxidant solution, thus ensuring a homogeneous mixture. The design of this machine is illustrated elsewhere [8].

The vitamin A and the sugar are placed into the mixer in the prescribed amounts and mixed for about 5 minutes. During this time, the necessary amount of antioxidant wax is dissolved in the oil, which is heated to 60°C. While dissolving, the antioxidant-oil mixture is maintained under a continuous stream of nitrogen. Once the wax is dissolved, it is flushed, while the mixer is still running, through the horizontal axis sprayers. Mixing is continued for 10 to 15 minutes, or until the mixture is homogeneous. The antioxidant-oil mixture is added through the sprayers to ensure a homogeneous mixture. After homogeneity is achieved, the premix is ready to be packaged until use. For packaging, a double black polyethylene bag is suggested, which, in turn, is placed inside another bag made of polypropylene fi-

TABLE 1. Composition of the vitamin A-sugar premix originally used in Guatemala

Component	% (w/w)
Vitamin A palmitate 250 CWS	22.000
Peanut oil ^a (peroxide free)	1.650 ^b
Antioxidant (Ronoxan A)	0.008
Sugar	76.342
Total	100.000

a. The peroxide content of the selected oil must not exceed 5 mEq/L. The following oils have been tested and considered adequate: corn, palm, soya bean, cottonseed, and sunflower [7].

b. Specific gravity 0.61.

bres. The bag is hermetically sealed, taking care to exclude any trapped air. Using the described set-up, a single operator can produce one batch of premix in 10 to 15 minutes. It is also suggested that the premix bags have a printed label clearly stating that the premix is not for human consumption and indicating the date of preparation and the lot number. The vitamin A content of each lot should be checked analytically. The final product should be a slightly yellow, uniform, free-flowing mixture, with no agglomerations or impurities, slightly oily but with no rancid odour.

Premix stability

A premix prepared by the procedure described above and kept in a dry place shielded from direct sunlight should be stable for a period of time in excess of the turnover of the fortified sugar, which is produced in a cyclical process carried out each year during the same season. Figure 1 shows the half-life of premixes prepared in Guatemala and El Salvador under different environmental conditions. The premixes were prepared with sunflower oil in Guatemala and cottonseed oil in El Salvador. The minimum half-life of the premix is 2.8 years, well in excess of the mean turnover time of sugar. However, sugar is generally not stored for periods longer than one year.

Sugar fortification

The procedure for sugar fortification consists of diluting the premix with sugar in a ratio of 1:1,000, which can be performed at any of several points during production. The proper amount of premix can be added to the centrifuges in which crystallized sugar is separated, the conveyors that move the crystallized sugar from the centrifuges to the dryers, or the rotating drum dryers to take advantage of the efficient mixing produced by the drying process [8]. Ideally, for accurate addition of the premix, a dosing machine, which has been prop-

erly calibrated to measure the correct proportions of premix and sugar and which stops automatically when there is no flow of sugar, should be used. Regardless of the point selected for addition of the premix, the mixing that occurs in the drying drums is enough to ensure the homogeneity of the fortified sugar. The drying process lasts for only short periods of time at temperatures below 80°C, so that the stability of the vitamin A in the fortified sugar is not affected. Once the sugar is fortified, it should be packed in containers that protect it from direct sunlight and excess humidity.

In the plant, quality control of the process should be continuous, and samples should be periodically analysed. The frequency of analysis depends on the amount of sugar produced and should be determined on a statistical basis. For quality control purposes, a number of field analytical procedures have been developed and tested to enable analysis of vitamin A content *in situ* in 1 to 3 minutes [8].

Stability tests carried out in Guatemala and in Basel, Switzerland, showed that vitamin A-fortified sugar can be directly heated to 100°C for periods of up to 15 minutes with no appreciable loss of activity. Syrups containing 55% to 65% fortified sugar heated for 1 hour at 80°C have shown losses of vitamin A activity on the order of 10% to 15%. Similar losses were observed in jellies containing fortified sugar that were cooked for 1 hour. When fortified sugar is dissolved at low pH values of 2 to 8 and heated, the loss of activity may reach 52%. On the other hand, when fortified sugar is used in hot coffee or tea prepared with boiling water and kept at this temperature for 10 minutes, the activity loss is only 1% to 2%. Storage of fortified sugar in commercially used bags for home distribution for up to six months at temperatures of 22° to 35°C and humidity levels of 70% to 85% saturation had no significant effect on vitamin A activity.

The biological activity of vitamin A-fortified sugar, compared with the standard vitamin A preparation used in trials employing experimental animals, yielded the same results for both preparations. In these tests, vitamin A-depleted rats were fed diets containing either fortified sugar or pure vitamin A palmitate. Both treatments had a similar capacity to restore plasma and liver retinol levels [8, 9].

Cost of fortification

Vitamin A palmitate accounts for up to 99% of the cost of the premix. At the present time, the estimated cost of the components of 1 kg of premix is approximately US\$8.10. Thus, the added cost to the selling price of sugar is on the order of US\$0.0081 per kilogram of fortified sugar.

In a meeting with representatives of the producers of vitamin A held in the Guatemalan offices of UNICEF,

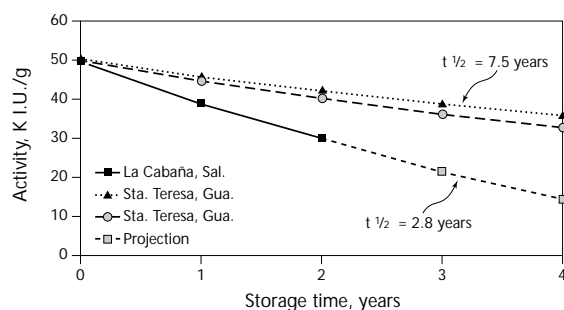


FIG. 1. Loss of vitamin A activity during storage of premixes prepared at two sites in Guatemala and El Salvador

the manufacturers made a commitment to maintain the price of vitamin A, subject only to changes in the value of the US dollar relative to the Swiss franc. This agreement has resulted in only small fluctuations in the price of the vitamin A palmitate 250 CWS used in sugar fortification. The changes in the cost per kilogram of the vitamin over the last 24 years are presented in figure 2 [8].

Newer technologies for sugar fortification

The procedures described above for the fortification of sugar are based on technology developed in the early 1970s and modified as needed over the following years. Problems that are generally encountered with this technology relate to poor conditions of preparation of premixes, low-quality oils with a high content of peroxides, and poor storage of the fortified sugar. The result, in spite of the use of antioxidants, is the slow development of rancidity of the added oil.

Several approaches have been taken to solve this problem. When saturated oils that remain in liquid form at room temperature are used, the fortified sugar remains stable. The small amount (about 0.08 µg/g) of saturated oil used as a binder in the fortified sugar does not have any negative nutritional implications. In many countries, this modification would be the best choice. A second approach involves using a dry mixing procedure in which no oil is used as a binder of the premix, thus eliminating the problem of peroxidation. This procedure is particularly useful when dealing with highly refined sugars. Several other binders are currently under investigation; one of the most promising seems to be micronized soluble polyvinyl pyrrolidone.

Fortification of sugar with iron

The characteristics of sugar that make it a good vehicle for fortification led to trials of fortification with

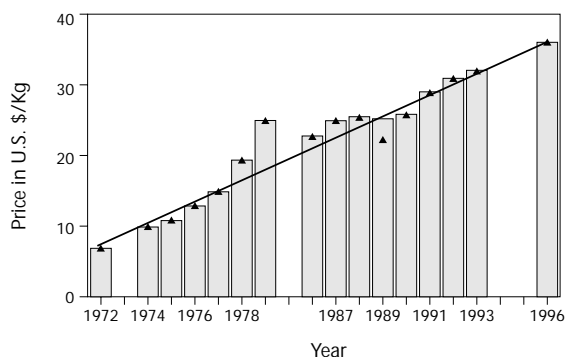


FIG. 2. Price of vitamin A palmitate 250 CWS from 1972 to 1996

iron compounds. In Guatemala during the mid-1970s, a trial of fortification of sugar with NaFeEDTA was carried out. At the time, this compound appeared to be promising, showing an apparent absorption of 3% to 8%. Sugar was fortified by directly adding 1 g of the chelate per kilogram of sugar. The iron content of the NaFeEDTA was 13%, resulting in the addition of 0.13 mg of iron per gram of sugar. Considering the maximal absorption of 8%, the amount of absorbable iron present was 0.01 mg per gram of sugar. With a mean sugar consumption of 36 g per person per day, a contribution of about 0.37 mg of absorbable iron per day from sugar was possible. However, after four years of consumption of this fortified sugar in three selected communities, the change in iron nutrition was only marginal [10]. Furthermore, there was a significant increase in the urinary excretion of zinc, copper, and iron (table 2).

The addition of NaFeEDTA to sugar resulted in an obvious change of colour, and the addition of NaFeEDTA-fortified sugar to foods, coffee, and tea also resulted in marked colour changes. Immediately after the addition of fortified sugar to coffee, the coffee turned deep blue. All these factors prevented the use of NaFeEDTA as a sugar fortificant.

More recently, a new tasteless chelate, in which iron is chelated with three molecules of glycine (iron tris-glycine chelate), has been used successfully to fortify sugar in Brazil where technology was developed for the industrial fortification of sugar. Iron-fortified sugar, using this compound, is now commercially available in Brazil [11]. With the tris-glycine chelate, there are no organoleptic changes, to the point that it can be used in highly refined sugar. No changes in colour are caused by the addition of this sugar to foods, including coffee.

In premixes containing oil prepared with the addition of NaFeEDTA, the maximum amount that can be used without adverse effects is 50%, and only through modification of the premix to contain 11% vitamin A for a final dilution of 1:500. Premixes of this type containing iron tris-amino chelate (FeAAC) can be prepared with a significantly lower iron content but can still maintain the same level of absorbed iron (table 3).

TABLE 2. Urinary excretion of iron, zinc, and copper after four years of consumption of sugar fortified with NaFeEDTA at a level of 1 mg/kg of sugar

Community	Urinary excretion of metal— mg/g creatinine (mean ± SD)		
	Fe	Zn	Cu
Control	36 ± 18	6 ± 10	3 ± 13
Community 1	112 ± 21	131 ± 34	51 ± 17
Community 2	126 ± 31	110 ± 32	104 ± 36
Community 3	134 ± 29	247 ± 59	41 ± 20

In terms of the percent iron content and its bioavailability, it is apparent that the amount of absorbable iron cannot be increased with NaFeEDTA fortification, but with the tris-iron chelate, the premix iron concentration can easily be increased to provide 100% or more of the daily requirement of absorbable iron.

By taking advantage of the technology developed for the dry mixing of nutrients and sugar, double-fortified sugar has been produced using vitamin A palmitate 250 CWS and iron tris-glycine chelate. Approximately 30% of this chelate, which contains 20% iron, is absorbed. The chelate has a very low toxicity; its LD₅₀ in rats is 17.0 g.

Iron bis-glycine chelate has been successfully used for fortification of whole cow's milk and corn and wheat flours. Field studies using milk fortified with 3 mg of iron from the chelate, without addition of ascorbate, have shown that up to 40% of the amino acid chelate is absorbed [12, 13]. Formal studies using water solutions of ⁵⁵Fe-labelled amino acid chelate proved that it is absorbed even better than the standard ferrous ascorbate, which was used as the absorption control, and that its absorption is regulated by the iron stores of the body [14].

Impact of vitamin A-fortified sugar on the population

In Guatemala the fortification programme was evaluated in its first phase in 1975, and it was shown that after 6 months of consumption of fortified sugar, there was a significant decrease in the prevalence of low plasma retinol levels, and after 12 months, the mean prevalence of these values in the population was below 5%.

TABLE 3. Comparison of premix compositions using NaFeEDTA and iron tris-glycine chelate, considering the iron content of each compound and the bioavailability of its iron

Composition	Premix FeNaEDTA (13% Fe)	Premix FeAAC ^a (20% Fe)
Components (g/100 g)		
250 CWS	11	11
Iron compound	50	12.5
Peanut oil	1.65	1.65
Ronoxan A	0.008	0.008
Sugar	37.342	74.842
Iron in premix	6.5	1.73
Absorbable iron	0.52	0.52
Premix dilution	1:500	1:500
Absorbable Fe/g premix	5.2 mg	5.2 mg
Absorbable Fe/g sugar	14.4 mg	10.4 mg

a. Iron tris-glycine chelate.

Similarly, the prevalence of human milk samples with less than 20 µg of retinol/dl was reduced by 50% in comparison with the levels before fortification. Human liver samples obtained from autopsies of persons killed in car accidents also showed a significant improvement in vitamin A content [8, 9].

After the reinitiation of nationwide sugar fortification in 1988, the first 6 months of the programme were evaluated (from November 1988 to May 1989). A comparison of the effects on plasma retinol levels in 1- to 7-year-old children in 1975 with those measured in 1989 is shown in figure 3. In the second evaluation in 1989, the adequacy of liver vitamin A concentrations was evaluated using the relative dose-response test. The response at this time point was similar to that observed in the first evaluation 14 years earlier, demonstrating the reproducibility of the effects of fortified sugar [8]. It is clear that through consumption of fortified sugar, the vitamin A status of a population can be improved within a relatively short time.

Now that the technology for the double fortification of sugar with vitamin A and highly absorbable iron tris-glycine chelate has been developed, it would appear that the control of iron deficiency and of iron-deficiency anaemia is also within reach. To illustrate the effectiveness of the iron amino acid chelates, the prevalence of iron-deficiency anaemia was reduced in some Brazilian populations from 70%–80% to 10%–15% after six months of consumption of whole milk fortified with iron bis-glycine chelate [13]. Studies carried out by the Secretary of Health of the state of São Paulo showed similar results, prompting the state to enact legislation making iron bis-glycine chelate fortification of the fluid milk used in Public Health Programs mandatory [12].

The cost of milk fortification is so low (US\$0.001 per litre) that similar programmes can be easily replicated in any population in which milk can be used as a vehicle for fortification. Wheat and corn flours have been fortified with bis-glycine chelate with similar re-

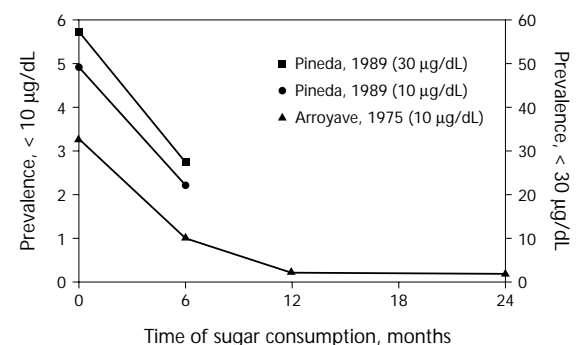


FIG. 3. Effect of consumption of vitamin A-fortified sugar on plasma retinol levels of one- to seven-year-old children in Guatemala [8, 9]

sults to those obtained with fortified milk. A number of different foods have been fortified with the chelated iron and are commercially available in Brazil, including sugar, milk, corn flour, wheat flour, cheese, yoghurt, cookies, and margarine.

In the development of these fortification programmes, the Latin American Centre of Nutrition and Metabolic Studies (Centro Latinoamericano de Nutrición y Estudios Metabólicos, CELANEM) has changed the usual mechanism for their establishment. Industry was initially approached and, with CELANEM, developed the fortification procedures to be used. Once industry

had been convinced that the quality of their products would not be altered and that they could effectively contribute to the solution of many public health problems, public health authorities were contacted and presented with ready-made solutions. All of the products described above were developed in this manner and are now available on the market. For example, milk has already been fortified in Argentina, Chile, Paraguay, Ecuador, Brazil, Colombia, Venezuela, and Mexico; it is available in Europe and will be fortified in the near future in China.

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New issues in developing effective approaches for the prevention and control of vitamin A deficiency

Martin W. Bloem, Saskia de Pee, and Ian Darnton-Hill

Abstract

Even mild to moderate vitamin A deficiency is now recognized as an important factor in child health and survival. This has given increased emphasis to the goal of virtually eliminating vitamin A deficiency and its consequences, including blindness, by the end of the decade. The implications of vitamin A deficiency, however, vary according to the group at risk, and this needs to be addressed when looking at ways to achieve the goal. In pre-school children, vitamin A deficiency can lead to increased risk of mortality and morbidity and to blindness. In pregnant and lactating women, it can lead to night-blindness and appears to have implications for maternal morbidity and mortality. Although the immediate health consequences for schoolchildren and adolescents are not completely known, they are probably less dramatic. Nevertheless, it is clear that there is a cross-generational cycle leading to and perpetuating vitamin A deficiency in affected communities. This also has implications when addressing prevention and control strategies. The existing, somewhat successful approach has been to target children aged six months to six years; it is implicit that this criterion is used to measure progress towards the end-of-decade goals. A broader, complementary, life-cycle approach to vitamin A deficiency is now appropriate in many countries. There is increasing emphasis on such approaches, i.e., fortifying foods with vitamin A and improving the diet, which address the whole population at risk. A mix of interventions will give governments the chance to shift from a subsidized vitamin A capsule programme to more sustainable, non-subsidized, consumer-funded vitamin A interventions, although in an appreciable number of countries, supplementation with vitamin A will be a ne-

cessity for some years to come. Guidelines to assist governments in such transitions are a high priority.

Introduction

Vitamin A deficiency has been known to be the underlying cause of xerophthalmia for many centuries. The recognition of the clinical signs has obscured the fact that subclinical vitamin A deficiency is prevalent among large segments of the populations of many countries. This deficiency critically affects the health and well-being of these societies, since a series of large intervention trials has shown that even mild to moderate vitamin A deficiency is an important factor in child health and survival [1].

The United Nations, through UNICEF, convened the World Summit for Children in September 1990 to discuss a plan of action for improving the condition of women and children worldwide. Over 70 heads of state ratified a global plan of action, which included 27 social and health goals to be achieved by the year 2000. The plan details how the rights of women and children to adequate and dignified survival and development can be guaranteed. Among the other goals were nutrition goals, including the virtual elimination of vitamin A deficiency and its consequences, including blindness. Two years later, the World Declaration and Plan of Action for Nutrition of the International Conference of Nutrition at Rome in December 1992 reaffirmed the goal of eliminating vitamin A deficiency before the end of the decade.

The question of why, amidst an abundance of plant sources of provitamin A, children still become blind from vitamin A deficiency was first raised by H.A.P.C. Oomen in Indonesia in the early part of this century. Lack of knowledge and lack of care were found to be the major underlying causes. However, it has recently become evident that the bioavailability of provitamin A from plant foods, especially from dark-green leafy vegetables and to some extent also from fruits and tubers, is much lower than what has been assumed [2-

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4]. In general, currently used food-composition tables overestimate the vitamin A content of dark-green leafy vegetables by a factor of approximately 4 to 6 [3, 4] and that of fruits by a factor of approximately 2 [3]. The degree of overestimation can range from as little as 1 to as much as 15, depending upon several factors, such as the method used for analysing carotene content, the food source of carotenoids, the preparation methods used, and the condition of the child (host) consuming the carotene source. However, whether it is a factor of 3 or a factor of 10, in countries where large segments of the population are dependent on dark-green leafy vegetables as their only source of vitamin A, there will be a high prevalence of subclinical vitamin A deficiency.

The implications of such vitamin A deficiency, however, vary according to the group at risk. In pre-school children, vitamin A deficiency can lead to increased risk of mortality and morbidity and to blindness. In pregnant and lactating women, it can lead to night-blindness and appears to have implications for maternal morbidity and mortality [5]. Although the immediate health consequences for schoolchildren and adolescents are not completely known, they are probably less dramatic (table 1).

The goal of this overview is to consider the implications of recognizing vitamin A deficiency as a potential problem in all age groups of a society rather than solely as a problem of pre-school children. This new paradigm—a life-cycle approach to vitamin A deficiency—will demonstrate the need for new strategies.

Assessment and analysis

The challenge of “virtually eliminating vitamin A deficiency and its consequences” has made governments face the need to determine the existence, severity, and extent of vitamin A deficiency in their populations. The reliability of such assessment depends on the validity and interpretation of the measures of vitamin A status employed. Vitamin A intake should be a leading indicator of vitamin A status at the population level, as a lack of vitamin A in the diet is the main underlying cause of vitamin A deficiency. However, because of the overestimation of dark-green leafy vegetables and

fruits as a source of vitamin A, among other limitations, dietary methodology has not proven to be a very useful assessment tool.

Serum retinol levels, although not considered a reliable index of the subclinical vitamin A status of individuals, have proven to be a useful indicator at a population level, thus demonstrating that indicators used for population-based assessment can be of limited value for individual-based assessment but can still be useful for characterizing a population. In contrast to subclinical vitamin A deficiency, which is prevalent in large portions (30%–70%) of affected populations, clinical vitamin A deficiency (xerophthalmia) is clustered in the lowest socio-economic strata of villages and communities in poorer countries. Nevertheless, the prevalence of xerophthalmia can still be used to identify vitamin A deficiency in a population, because a population with an overall high prevalence of xerophthalmia will have an overall high prevalence of vitamin A deficiency. Xerophthalmia can be viewed as the tip of the iceberg for vitamin A deficiency (table 2).

Cut-off points are applied to laboratory findings for individual-based screening to estimate the prevalence of the condition of interest, in this case vitamin A deficiency. The only conventional and widely accepted biochemical criterion for the identification of populations at risk is a prevalence of 5% or more of serum retinol levels less than 10 µg/dl. A serious drawback of this approach is the tendency to regard only individuals below the cut-off as affected, and to focus intervention on those who meet the definition for the indicator, when in fact a much greater proportion of the population is affected. One way to avoid this pitfall is to present the entire distribution of the laboratory findings against a reference or standard distribution (which should be in a population largely free from vitamin A deficiency). The proper application of the prevalence of an indicator below a certain cut-off point is to view its prevalence as an index of the severity of the deficiency in the population.

Prevalence

Vitamin A deficiency is one of the most frequent nutritional deficiency disorders in the world. The World

TABLE 1. Public health implications of vitamin A deficiency according to risk group

Variable	Infants (6–12 mo)	Pre-school children	School-children	Adolescents	Pregnant women	Lactating women
Mortality	+	+	?	+	+	+
Severity of morbidity	–	+	?	?	+	+
Mild anaemia	±	+	+	+	+	+
Growth	?	±	?	?	?	–

TABLE 2. Biological indicators of vitamin A status

Indicator	Infants	Pre-school children	School-children	Adolescents	Pregnant women	Lactating women
Clinical signs	-	+	Night-blindness, Bitot's spots	Night-blindness?	Night-blindness	Night-blindness
Serum retinol	+	+	+	+	+	+
Breastmilk vitamin A	Indirect indicator?					
Vitamin A-related morbidity		+			+	+

Health Organization (WHO) has estimated that over 250 million children worldwide have deficient vitamin A stores [1]. The highest prevalence of vitamin A deficiency is found in pre-school children and in pregnant and lactating women, but subclinical vitamin A deficiency has also been shown to be common in school-children and adolescents in some settings. Almost all country prevalence data relate to vitamin A deficiency in pre-school children, which means that prevalence data from other age groups are frequently not available (table 1).

Requirements

Vitamin A is the generic term for all compounds that have the biological activity of retinol. In animals vitamin A exists largely in the preformed state as retinol or as its related compounds. In plants vitamin A occurs in the precursor or provitamin forms as carotenoids, which animals convert into preformed vitamin A after consuming them in the diet. The most widely distributed carotenoid is β -carotene. The relative amounts of vitamin A consumed as provitamins from plant sources and as preformed vitamin A from animal sources differ considerably in various parts of the world (table 3). In the average Western diet, about half of the vitamin A

activity comes from plant carotenenes. The remainder of the dietary vitamin A is obtained as preformed vitamin A from animal sources. In much of the developing world, up to 90% of the vitamin A in the diet is of plant origin. Sources of the provitamin A carotenoids include dark-green leafy vegetables, deep-yellow vegetables, and deep-yellow fruits. Sources of preformed vitamin A include liver, fish liver oil extracts, and egg yolks.

The apparent vitamin A activity of plant foods was recently been found to be much lower than had been assumed [2, 3]. An intervention study among school-children in Indonesia found that the apparent vitamin A activity of leafy vegetables and carrots was 23% of what had been assumed (95% confidence interval, 8% to 46%), and that the vitamin A activity of fruits was 50% of what had been assumed (95% confidence interval, 21% to 100%) [3]. These proportions were confirmed in a recent intervention study among breastfeeding women in Vietnam [7]. Vitamin A from plant sources largely comes from leafy vegetables and to a much smaller extent from roots, tubers, and fruits. In fact, recent analysis of cross-sectional data from women in Indonesia confirmed that the apparent vitamin A activity of plant foods was 16% to 23% of what had been previously assumed [4]. Therefore, we have chosen a factor of approximately five for adjusting vitamin A intake from plant foods.

TABLE 3. Available supply of vitamin A according to WHO region

Region	Vitamin A (mg RE/day) ^a			Incidence of xerophthalmia
	Vegetable	Animal	Total	
South-East Asia	378 (75)	53	431 (128)	1.45
Africa	654 (130)	122	776 (255)	1.04
Western Pacific	781 (156)	216	997 (372)	0.13
Eastern Mediterranean	591 (118)	345	936 (463)	0.12
Americas	519 (104)	295	814 (400)	0.06

Source: ref. 6.

a. Numbers in parentheses are adjusted for bioavailability.

Table 3 shows the vitamin A intake and the xerophthalmia rates by region. The gross figures do not show a significant correlation between the total vitamin A intake and reported rates of xerophthalmia (Spearman rank test, $R = .60, p = .285$). However, the adjusted vitamin A intake for the new conversion factor correlates significantly with the prevalence rates of xerophthalmia (Spearman rank test, $R = .90, p = .038$).

Causes of vitamin A deficiency

Figure 1 shows the conceptual framework of the causes of vitamin A deficiency. The conceptual framework of the causes of xerophthalmia is in principle the same. However, the role of contributing factors such as infection and protein–energy malnutrition is more important.

The main causes of vitamin A deficiency in the de-

veloping world are insufficient intake of vitamin A and poor bioavailability of provitamin A sources (vegetables and fruits). Important contributing factors to vitamin A deficiency are the increased requirements for vitamin A at certain stages in the life cycle (early childhood, pregnancy, and lactation) and during infection.

However, this simplified list does not address the many varied physiological, sociocultural, and geographic factors that also define the vitamin A status of a population. The conceptual framework clearly shows the role of the contributing factors. Coexisting health status affects vitamin A status both by affecting the metabolic processes and by reducing intake. The clustering of xerophthalmia, now widely described, points to the importance of sociocultural factors such as intrahousehold distribution. The different prevalence in boys and girls points to the impact of sex and intrahousehold distribution of food.

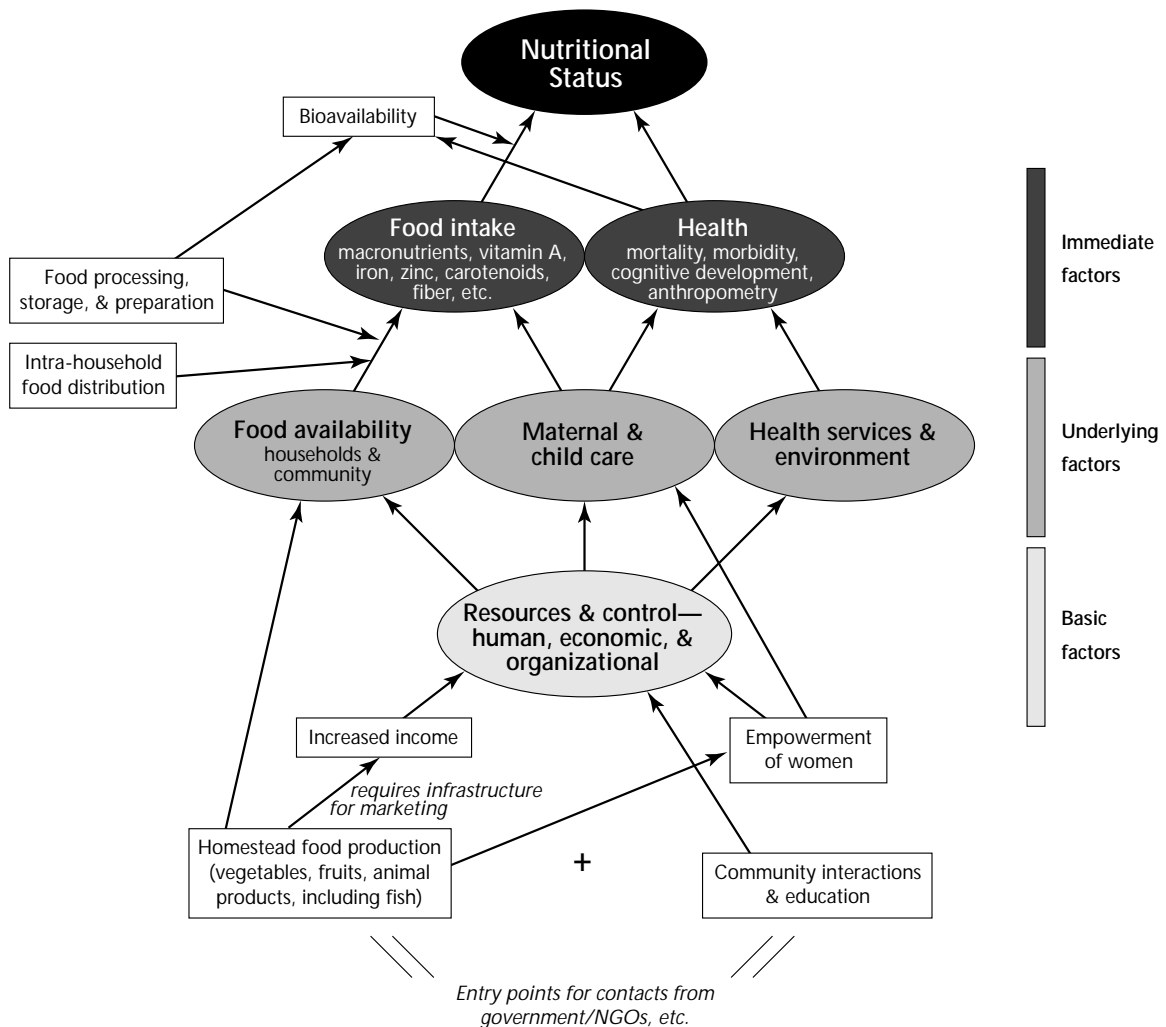


FIG. 1. Conceptual framework of causes of vitamin A deficiency

Consequences of vitamin A deficiency

Vitamin A deficiency and child mortality

Irreversible blindness is among the most dramatic consequences of vitamin A deficiency. As a result, there has been considerable emphasis on xerophthalmia, the eye changes due to vitamin A deficiency, and the most visible consequences of vitamin A deficiency. Nutritionists have tended to consider xerophthalmia a problem for those working in blindness prevention, whereas those involved in blindness prevention have considered it a problem for nutritionists. More recently, though, on the basis of the work of Sommer and others, vitamin A has become recognized as having an essential role in the prevention of childhood mortality and disability [1].

A series of eight controlled, community-based trials has been carried out since the first trial in Aceh [8-15]. Findings from all these trials were submitted to a comprehensive meta-analysis on the effectiveness of vitamin A supplementation in reducing child morbidity and mortality [16]. The reported impact has ranged from a 50% reduction in mortality rates among children under five years of age (Tamil Nadu) to no effect (Sudan). The meta-analysis, which included 8 of 10 formal field trials, showed a 23% reduction in mortality (95% confidence interval, 15% to 29%) for children aged 6 to 72 months. Estimated 95% confidence intervals were established under two models: a fixed effects model ($R = .77$; 95% confidence interval, .71 to .84) and a random effects model ($R = .77$; 95% confidence interval, .68 to .88).

Adequate vitamin A status prevents nutritional blindness and contributes significantly to child health and survival. Vitamin A plays an important role in preventing nutritional blindness and in reducing morbidity and mortality, from mid-infancy through the early school-age years, particularly from measles and diarrhoea.

Vitamin A deficiency and morbidity

The various studies on the association between vitamin A deficiency and morbidity have not had very consistent results [17-26]. This may be explained by the fact that morbidity studies are hard to carry out. Under- and overreporting, differences in definitions and severity, and differences in underlying factors such as malnutrition make these studies more difficult than studies on mortality, which have, among other things, the clearly defined end point of death. However, the lack of findings cannot be attributed only to poor methods, since studies of the effects of improvements in water supplies and excreta disposal were able to detect a reduction of 22% in morbidity rates using similar methods.

Increased morbidity and mortality occur at levels of vitamin A deficiency less severe and chronic than those

required for night-blindness and xerophthalmia. Therefore, the definition of vitamin A deficiency for public health purposes must be revised and made more sensitive to milder degrees of deficiency.

Vitamin A deficiency and measles

Measles deserves separate consideration because it is a viral disease that infects and damages epithelial tissues throughout the body, and because it has been shown that measles plays an important role in corneal blindness. A relationship between measles and vitamin A has been recognized since the early 1930s [27]. It is now well known that measles can bring serum concentrations of vitamin A in well-nourished children to below those observed in non-infected malnourished children. Mean serum retinol levels have been shown to be significantly lower in children with corneal lesions than in those with normal corneas. Several studies have evaluated the treatment of severe measles with vitamin A [27-29]. In these trials, mortality was at least 50% lower among children who had been treated with large doses of vitamin A at admission. In each trial, the clinical severity of measles complications was lower among those who survived.

Vitamin A deficiency increases the severity, complications, and risk of death from measles. Improving vitamin A status before the onset of measles (prophylaxis), or after measles occurs (treatment), markedly reduces the severity of complications and associated mortality. Improving the vitamin A status of children with vitamin A deficiency and treating all cases of measles with vitamin A, even in populations in which xerophthalmia is rare, can substantially reduce childhood disease and mortality.

Vitamin A deficiency and women

Although vitamin A deficiency is a serious and dangerous deficiency in childhood, it has recently been recognized that its impact goes well beyond this age group. Publications from Indonesia and Malawi, and now Nepal, have shown that vitamin A deficiency in pregnancy is associated with anaemia, low vitamin A content of breastmilk, transmission of the human immunodeficiency virus (HIV) from mother to child [30-32], and probably a reduction in maternal mortality [5]. Stoltzfus et al. [31] showed that a high dose of vitamin A was an efficacious way to improve the vitamin A status of both mother and child. Suharno et al. [30] demonstrated the extent to which improvement in vitamin A status contributes to the treatment of anaemia in pregnancy. Semba et al. [32] showed that the mean vitamin A status of mothers who transmitted HIV to their infants was lower than that of mothers who did not transmit HIV.

These reports are of less public health importance

when vitamin A deficiency in women is not very prevalent. A recent analysis from Bangladesh, however, showed that the prevalence of night-blindness among mothers was even higher than among pre-school children. Children of mothers with night-blindness showed a statistically significant increase in morbidity after potential confounding factors had been controlled [33]. Similar results have been reported in Nepal [34, 35]. A recent study by West et al. [12] showed that vitamin A or β -carotene supplementation to pregnant women may reduce maternal mortality by up to 50%.

It is well recognized that vitamin A deficiency clusters in households and is more likely to occur in siblings, and that children from the same household exhibit similar vitamin A status. It is, therefore, not surprising that this cluster effect extends to other vulnerable family members, notably women of reproductive age. It takes one to two years for a healthy adult to show signs of vitamin A deficiency, thereby making it likely that many of these mothers have been nutritionally compromised since their early childhood. In life-cycle terms, this means that young girls are starting out with low liver stores of vitamin A and never have a chance to catch up. By the time they are 18 and married, they too will give birth to children with low vitamin A stores. These children, a majority of whom are breastfed exclusively for the first months of life, then complete the generational cycle of vitamin A deficiency. Older and malnourished women in such societies have also been found to be at risk for night-blindness, which reinforces the above-mentioned hypothesis and emphasizes the need to take a life-cycle approach to vitamin A deficiency.

Vitamin A deficiency is prevalent among women in areas where vitamin A deficiency is endemic. Vitamin A deficiency in women has negative effects on the health status of both mothers and their offspring. Therefore, programmes should be developed to improve the vitamin A status of women, starting in early childhood and continuing during the reproductive years, for the sake of both their own and their children's health. Vitamin A interventions in pregnant women may reduce maternal mortality by up to 50%.

Vitamin A deficiency and anaemia

Vitamin A and its derivatives are important not only for the normal functioning of the eye but also for the normal differentiation of other cell systems in the body, including parts of the haematological system. Arrays of epidemiological studies have indicated that vitamin A deficiency and anaemia often coexist, and that there are significant associations between serum retinol and biochemical indicators of iron status [36-44]. A study of pregnant Indonesian women showed that 100% of the anaemic women were cured by combination therapy of vitamin A with iron, whereas only 40% were cured by vitamin A alone and only 60% by iron alone [40]. This clearly has important programmatic and policy implications. Recent work from Nepal by Stoltzfus et al. [45] showed that vitamin A supplementation improved only mild anaemia, and only in those women who were not infected by worms.

Improvement of iron status, when combined with vitamin A supplementation, will have an even greater impact on the prevalence of anaemia than the separate application of only one of these strategies. Vitamin A deficiency should be tackled by a combination of strategies, including dietary diversification, food fortification, vitamin A supplementation, and other public health measures such as promotion of breastfeeding and control of infectious disease, to achieve the virtual elimination of vitamin A deficiency (table 4).

Supplementation

The rationale for supplementation with high doses of vitamin A (retinol) rests on the fact that this fat-soluble nutrient can be stored in the body, principally in the liver. Periodic high-dose supplementation is intended to protect against vitamin A deficiency and its consequences by building up a reserve of the vitamin for periods of reduced dietary intake or increased needs [46].

TABLE 4. Strategies to combat vitamin A deficiency according to risk group

Strategy	Infants (0-6 mo)	Pre-school children	School-children	Adolescents	Pregnant women	Lactating women
Breastfeeding	++	+	-	-	-	-
Universal distribution of high-dose vitamin A	±	+	Not yet	Not yet	-	Postpartum
Low-dose vitamin A	+	+	+	+	+	+
Food-based	-	+	+	+	+	+
Fortification	+	+	+	+	+	+

High-dose vitamin A supplements for pre-school children, lactating women, and high-risk populations

The human liver has an enormous capacity to store vitamin A, allowing sufficient stores in the body to be laid down through periodic administration of large doses of the vitamin. The dose of vitamin A must be large enough to offer protection but not so large as to produce side effects. For individuals one year of age and older, administration of 200,000 IU (approximately 60,000 mg) of vitamin A will provide adequate protection for four to six months. There is now considerable experience with vitamin A supplementation programmes in countries such as Bangladesh and India, and they are known to be effective and safe. When vitamin A is administered in recommended doses, there are no serious or permanent adverse effects; such side effects as may occasionally occur (e.g., for infants, a tense or bulging fontanelle or vomiting) are minor and transitory and do not require specific treatment [46].

All mothers in high-risk regions should also receive a high dose of vitamin A within eight weeks of delivery. The capsule should be delivered as soon as possible after delivery, since this will increase the vitamin A levels in breastmilk [31]. It now appears this may also have beneficial effects for the mother herself [5].

Infants and children who have infections such as diarrhoea, measles, respiratory infections, and chickenpox or who are severely malnourished have an increased risk of vitamin A deficiency. Furthermore, work from Bangladesh, Indonesia, and Nepal has shown that severe vitamin A deficiency is clustered. It is, therefore, recommended that these children receive a high dose of vitamin A.

Low-dose vitamin A supplementation

Both severe vitamin A deficiency and excessive vitamin A are teratogenic in animals, although this observation has not been confirmed in humans. Adequate maternal vitamin A status ensures protection from the adverse consequences of either too much or too little vitamin A for the mother, foetus, and newborn [47]. Where habitual vitamin A intakes are low, a pregnant woman and her developing foetus are expected to benefit without risk from a daily vitamin A intake of 10,000 IU or a weekly intake of 25,000 IU from diet or supplementation or a combination of both. It has been suggested by Underwood and others (e.g., at the International Congress of Nutrition in Montreal in 1997) that these somewhat more physiological doses may have an added advantage over the high-dose regimens. A weekly dose was the method used in a recent study in Nepal showing an impact of both vitamin A and carotene separately on maternal mortality [5]. This also suggests that the form of the supplement may be relevant.

Fortification

Micronutrient interventions, particularly fortification, have been identified by the World Bank as among the most cost-effective of all health interventions [48]. There is a wealth of experience in the fortification of foods, and it has been a major factor in the control of micronutrient deficiencies in the industrialized world [49]. Until recently it was presumed that fortification was not a suitable intervention in the less industrialized countries, as the experience in developing countries has not always been encouraging [50]. There are now enough successful examples to suggest this is no longer true. Mora and Dary^{*} list 17 countries in Latin America that now fortify with at least one micronutrient and sometimes more.

Vitamin A fortification has been important in reducing deficiencies of vitamin A, especially in Latin America, where sugar is fortified. Other vehicles have included fats and oils, tea, cereals, monosodium glutamate and instant noodles, as well as milk and milk powder, whole wheat, rice, salt, soya bean oil, and infant formulas [51]. For example, margarine is currently fortified with vitamin A in Brazil, Chile, Colombia, El Salvador, Mexico, the Philippines, and other countries around the world, including virtually all developed countries. In India red palm oil is added to other edible oils, and vitamin A-fortified soya bean oil is being tested in Brazil [52].

The most successful experience with vitamin A, outside the industrialized world where margarine and milk have been most important, is with sugar in Central and South America. Sugar was first fortified in Guatemala over 25 years ago. Despite the demonstrated success of the programme in the early 1970s, with increases in the status of recipients' vitamin A levels and, indirectly, haemoglobin levels, the programme faltered in the 1980s [53]. This was due to a lack of continuing government commitment, indifference from the producing sector, economic limitations, and, presumably, a lack of self-sustainability (in terms of passing on costs, etc.), so that it could not continue without some public-sector involvement. It has now been revitalized, although some technical improvements are still needed. In a start-up programme in Bolivia, in a partnership between government, donors (US Agency for International Development/OMNI, UNICEF), and a commercial firm, sustainability has yet to be assured, although there are currently plans for scaling up nationally by the private sector. Sugar has been fortified with vitamin A in Costa Rica, El Salvador, Guatemala, Honduras, and Panama [51]. Zambia has reached agreement to fortify its sugar in 1998. Other countries, such as the Philippines and Uganda, are also interested.

^{*}Mora JO, Dary O. Strategies for prevention of micronutrient deficiency through food fortification. Lessons learned from Latin America. Presented at the 9th World Congress of Food Science and Technology, Budapest, Hungary, 1995.

An interesting programme using whole wheat was developed in Bangladesh with technical assistance and support from the US Agency for International Development through Helen Keller International. Wheat being the less preferred staple, the fortification programme would have been automatically targeted to the poor. It became, however, an example of a technically feasible, properly developed programme that failed politically because it did not adequately involve the policy makers and those most affected [54]. The Philippines is currently testing vitamin A fortification of wheat flour.

In both Indonesia and the Philippines, fortifying monosodium glutamate (MSG) with vitamin A had been shown to be technically feasible and had been properly developed by consumption, taste, and impact trials [55, 56]. It did not proceed because of a variety of technical, political, and food-industry reservations. Fortification of rice and other cereals is also technically feasible as a pilot, but the fortification of rice with vitamin A has not proceeded to the national level. In Brazil it is still at the stage of bioavailability testing [51]. In Venezuela, on the other hand, pre-cooked corn flour, used to make *arepas*, a staple food in the national diet, has been successfully fortified with vitamin A, iron, thiamine, riboflavin, and niacin [57].

Success in fortifying with vitamin A has depended on sustained political commitment (both in-country and, initially, by donors), persistence with technical development of fortificant technologies to overcome problems, and increased awareness of the health consequences of vitamin A deficiency by governments as well as involvement of the private sector. It has, however, now been shown to be effective in a variety of settings [51-53, 58].

Food-diversification programmes

Since inadequate intake of vitamin A is the main cause of vitamin A deficiency, the solution lies in providing adequate amounts of the vitamin to populations at risk. Vitamin A in foods consists of provitamin A sources and preformed vitamin A sources. Foods containing preformed vitamin A are expensive and beyond the regular reach of the poor, but alternative, less expensive sources of provitamin A are easily available. Home gardening is a traditional family food production system widely practised in many developing countries [59-61].

Despite this, vitamin A deficiency remains a public health problem in many of these countries. Provitamin A carotenoids are the major source of dietary vitamin A, with plant sources providing more than 80% of the total vitamin A intake. The intervention studies mentioned above have shown that leafy vegetables and carrots improve vitamin A status, but not as much as previously thought [3]. Fruits, including pumpkin and sweet potato, improve vitamin A status more than veg-

etables. This, the lower bioavailability of vitamin A in vegetables and fruits, and probably also the seasonal variability of production of vegetables and fruits in home gardens, are factors underlying the causes of vitamin A deficiency in these regions. However, vegetables and fruits are more than a possible source of vitamin A; the various carotenoids and other micronutrients they contain are important, because consumption of vegetables and fruits is associated with lower risk of degenerative diseases. A recent study in Nepal also showed that β -carotene had an effect on reducing maternal mortality, which is not the case for vitamin A [5].

It is, therefore, essential to maximize the effectiveness of home gardening as a strategy to combat vitamin A deficiency. Anecdotal experience suggests that home gardening (as a method of improving nutrition) has been generally successful at the pilot phase but has not often been scaled up successfully. Recent experience in Bangladesh, however, has demonstrated a successful example [60]. The International Union of Nutritional Sciences (IUNS) Committee II/B Food Gardening for Nutrition Improvement has made the following recommendations:

- » Diversify food production
 - Where possible, include orange fruits, roots, and tubers;
 - Where possible, introduce animal husbandry, such as poultry and fish;
- » Optimize the effect of vegetables through
 - Deworming;
 - Providing zinc supplements (which may improve carotene bioconversion, but this needs further research);
 - Maximizing nutrient intake and reducing the effect of matrix and absorption inhibitors by choice of foods and choice of preparation methods;
 - Using techniques of breeding, selection, and genetic engineering to improve carotene content and bioavailability.

Implementing small-scale horticultural strategies to increase effectiveness raises questions not always considered in nutrition and health programmes. These include agricultural issues (fences to keep chickens away from seeds and seedlings, seasonality in production, the need for preservation, etc.) and the feasibility of such measures as flood control, which alters conditions for fish farming, altering food practices, such as the consumption of fruits that are prematurely used as vegetables, and, perhaps most importantly, community-level constraints, such as socio-economic conditions. It is also suggested that where there is a traditional practice of home gardening, using such an approach to increase micronutrient intake is more likely to be successful.

Using vitamin A capsule programme evaluation to monitor progress in food-diversification and food-fortification programmes

For two decades now, at least four countries in South-East Asia (Bangladesh, India, Indonesia, and Vietnam) have had programmes implementing universal supplementation of vitamin A capsules, which, according to the World Bank, is one of the most cost-effective of health interventions. Although prophylactic vitamin A dosing does not address the underlying cause of vitamin A deficiency, the nutritional aim is to improve vitamin A status for several months by increasing liver stores and tissue concentrations of retinol, thereby reducing the risk and severity of vitamin A deficiency and its devastating sequela of blindness, as well as reducing the increased morbidity and mortality from infectious diseases as a consequence of vitamin A deficiency, while minimizing the risk of acute hypervitaminosis A.

Several studies have shown that high-potency vitamin A supplementation has an efficacy of 90% under controlled circumstances [62-65]. The reasons that the efficacy of vitamin A capsules is not 100% may be an inability of 200,000 IU to protect individuals who are at particularly high risk (repeated infections, virtual absence of dietary sources, or severe deficiency initially) for the full six months or programme-related issues (inadequate administration, misrecording, or partial delivery of the intended dose). The likely cause of early recurrence of vitamin A deficiency after a high-dose vitamin A capsule is poor dietary intake of vitamin A combined with infectious diseases.

Since the efficacy of vitamin A capsules is 90%, the effectiveness will reflect differences in programme performance under "real-life" circumstances. The theoretical effectiveness, or the expected reduction, is the product of efficacy and coverage. Two recent studies in the region studied the effectiveness of vitamin A capsule programmes [64, 65]. A study from Bangladesh found an effectiveness of 25%, with coverage of 48% in rural areas, and a higher effectiveness of 61%, with coverage of 93% in urban areas. The expected reductions under these circumstances were $90\% \times 48\% = 43\%$ and $90\% \times 93\% = 83\%$, respectively [1]. The lower effectiveness is most probably due to the low dietary vitamin A intake and high rate of infectious disease among pre-school-aged children in Bangladesh. The effectiveness of the vitamin A capsule programme was associated with the time lag between the distribution of the capsule and the moment of measurement of the impact. This implies that vitamin A supplementation would be more effective when given every four months.

During the past 10 years, substantial progress has been made, particularly in reducing the prevalence of vitamin A deficiency. The analysis of both the Bangladesh

and Vietnam experiences showed that in terms of high effectiveness (Vietnam) or of a high time-response effectiveness (Bangladesh), the reduction in vitamin A deficiency in those countries has been mainly an effect of the vitamin A capsule programme, and that the underlying problem of lack of vitamin A in the diet (through fortification or through foods in the diet) has still not been solved. The governments, however, are now in the process of phasing out the vitamin A capsule programme, because the national prevalence of vitamin A deficiency is currently below the level that has been used to define the existence of a public health problem.

As the intake of vitamin A-rich sources in the diet increases as a result of fortification, changing diets, or both, the efficacy of vitamin A capsule supplementation will decrease (in Europe there is no impact of vitamin A supplementation on morbidity, mortality, or blindness). As a consequence, the effectiveness of the vitamin A capsule programme will decline with maintained coverage rates. Measuring the effectiveness of vitamin A capsules is much simpler than measuring the shift in a variety of fortified products or natural sources of vitamin A. Work is currently under way to measure the relative cost-effectiveness of different interventions. In the past, sustainability has not always been factored in, nor has the changing burden of costs (moving from donors to consumers).

The future

Several countries (Indonesia, India, and the Philippines) have made serious progress, at least at the national level, in eliminating xerophthalmia. All still have significant problems with vitamin A deficiency, as detected by serum retinol surveys. It is known that this must be having an impact on both morbidity and mortality of young children. However, it is likely that schoolchildren, adolescents, and women (especially pregnant and lactating women) will also show signs of vitamin A deficiency upon examination. The previous, largely successful approach has been to address children six months to six years of age (and it is implicit that this is the criterion being used to measure progress towards the end-of-decade goals). It is becoming clear that a broader, complementary life-cycle approach to vitamin A deficiency is now appropriate in many countries.

Over the last few years, there has been increasing emphasis on approaches such as fortifying foods with vitamin A and improving the diet of the population at risk. A mix of interventions will give governments the chance to shift from a subsidized vitamin A capsule programme to more sustainable, non-subsidized, consumer-funded vitamin A interventions. In an appreciable number of countries, supplementation with vitamin A will be a necessity for some years to come. Nevertheless, governments are seeking guidelines for

phasing out the vitamin A capsule programme when fortification and other approaches emerge. Monitoring food-based strategies and fortification programmes is much more costly and perhaps not very cost-effective. Guidelines to assist governments in such transitions are a high priority.

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Update on rice fortification in the Philippines

Rodolfo F. Florentino and Ma. Regina A. Pedro

Abstract

Rice, the staple in all regions in the Philippines, is an excellent vehicle for fortification. The Food and Nutrition Research Institute developed the technology for the fortification of rice with iron, using ferrous sulphate as the fortificant. A prototype machine was manufactured for the production of iron-fortified premix with a capacity of 200 kg per batch. A study on iron bioavailability showed a significant increase in the amount of iron absorbed with iron-fortified rice. A clinical trial conducted with 173 schoolchildren for six months showed a greater increase in haemoglobin in subjects who received iron-fortified rice than in those who did not. The problems and constraints that arise with rice fortification include the added cost of fortification (estimated at 2.5% of the cost of rice), which would probably be passed on to the consumer, and the presence of numerous rice mills throughout the country, which may pose difficulties in enforcement. Nevertheless, when carried out in large rice mills, fortification of rice with iron could reach a significant portion of the population.

Introduction

Micronutrient malnutrition is now the focus of the world's nutrition community because of its largely covert deleterious effects on large portions of the population, including physical and mental deformities, high risk of infection, low work productivity, and increased mortality in young children: hence the term "hidden hunger." Iron deficiency is the most widespread of the micronutrient deficiencies. Over 2,000 million people in practically all countries of the world are affected [1].

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Mention of the names of firms and commercial products does not imply endorsement by the United Nations University.

In the Philippines, 50% of children 6 to 11 months of age and more than 40% of pregnant and lactating women and the elderly are anaemic [2].

Several control measures against iron deficiency have been identified and are being carried out to a varying extent in different countries. Iron supplementation has been shown to be a successful intervention in the short term, but problems of limited outreach and sustainability as well as poor compliance constrain its implementation on a large scale. The nutritional improvement of the food supply and the alleviation of poverty, coupled with the modification of diets through nutrition education, offers a more permanent alternative, but it will take a long time before that objective is realized. On the other hand, fortification, a strategy geared towards improving the nutritional quality of the food supply, has been found to be effective and feasible when the vehicle chosen is widely consumed by the population at risk. Thus, efforts to fortify rice with iron have been pursued in the Philippines as a medium-term strategy for the control of nutritional anaemia, mainly by the Food and Nutrition Research Institute (FNRI).

In the Philippines rice is an excellent vehicle for fortification, because Filipinos are basically rice-eating people regardless of income. Rice is the staple food in all regions of the country, although it is commonly combined with corn in the central Philippines. It is consumed in relatively constant amounts by each age and sex group. The average daily consumption is 308 g overall and 143 g for children six years of age or younger [3]. People with low income consume proportionately more rice than those with higher incomes. However, people in low-income groups are more at risk for both protein-energy malnutrition and micronutrient malnutrition. Therefore, if fortified rice was distributed to the general population, it would reach practically every Filipino.

Another advantage of rice is that its consumption is not restricted in people with certain medical conditions, unlike other potential vehicles such as sugar (restricted in people with diabetes) and fish sauce, fish paste, and salt (restricted in people with renal disorders and hypertension).

However, rice cultivation and milling in the Philippines, as in other developing countries, are not centralized. Rice is cultivated predominantly in small farms and milled in some 11,000 rice mills throughout the country. Home pounding still accounts for a small portion of rice consumption among some farming households who cannot afford milling fees. Such issues thus need to be addressed in the design of the delivery system. However, as suggested by Austin [4, 5], decentralized milling could permit geographical targeting and reduce overcoverage.

History of rice fortification in the Philippines

Rice enrichment in the Philippines began in the mid-1940s, when it was first conceived by Dr. R.R. Williams, the discoverer of vitamin B₁, and then by the Secretary of Health of the Philippines, Dr. Juan Salcedo, Jr. At that time, the process for adding thiamine, niacin, and iron to rice had been developed by Hoffman-La Roche. Also during this time, beriberi was a major public health problem in the country, and with the development of technology to fortify rice with thiamine, a promising solution to the beriberi problem presented itself.

In 1946 experiments on rice fortification in the Philippines began. Preliminary feeding trials among government employees, members of the armed forces, and children in welfare institutions showed that rice enriched with thiamine, niacin, and iron was acceptable with regard to colour, taste, odour, palatability, and digestibility. A larger-scale pilot test of rice fortification was done in the province of Bataan. Rice was enriched at the mill and the household levels in half of the province, while the other half served as control. Significant reduction in mortality from beriberi was noted in the experimental area after one year of implementation, and the virtual elimination of mortality from beriberi was recorded in the second year. The prevalence of the disease was drastically reduced as well.

The success of the Bataan Rice Enrichment Experiment led to the enactment of the Rice Enrichment Law in 1952, which required that all rice millers and wholesalers enrich the rice they milled or traded. The rice millers, however, saw the law as a way for their total production and thus their taxable income to be monitored, since every 50-kg bag of premix that they obtained from a government centre indicated 200 bags of rice milled. Non-compliance by rice millers was a major setback to the enforcement of the law. Moreover, since rice millers and traders constituted a formidable bloc in the country's political structure, the political will to enforce the law also wavered. This was coupled to the high cost of monitoring for compliance by retailers throughout the country. Thus, rice enrichment died a natural death. Fortunately, by the end of

the 1950s, beriberi had all but disappeared from the country. To this day, the law has not been repealed.

Interest in rice fortification was revived in the early 1980s because of recognition of the efficiency of food fortification for the control of micronutrient deficiencies, including iron-deficiency anaemia, which is rampant in the country. Therefore, the FNRI modified and adapted the technology used in the government's previous attempt to fortify rice with ferrous sulphate.

Technology

Payumo et al. [6] of the FNRI established the technical process of fortifying rice with iron using ferrous sulphate as the fortificant and a suitable coating treatment that minimized nutrient losses (9%) due to washing of grains in preparation for cooking. At a fortification level of 12 mg of iron per gram of premix rice and a 1:200 ratio of premix to ordinary milled rice, the enriched rice was rated acceptable even after six months of storage at room temperature. The study by Marzan et al. [7] of iron absorption with different levels of iron-fortified rice showed that at a 0.5% level of fortification (1:200), about 12% iron absorption was achievable among normal adult males.

Meanwhile, through the Philippine Plan of Action for Nutrition (PPAN), the Philippines committed itself to reduce significantly, if not eradicate, micronutrient malnutrition, specifically deficiencies in vitamin A, iron, and iodine. The PPAN identified food fortification as among the interventions the country would vigorously pursue.

Initially, the national rice-fortification programme planned to implement a fortification level of 12 mg of iron per gram of premix rice, which aimed to provide 100% of the recommended dietary allowance (RDA) for iron, given a 1:200 mixing ratio with ordinary milled rice and a per capita consumption of 300 g of rice per day. However, adults, and sometimes adolescents and children, may consume more than 300 g of rice per day and may, therefore, get more than 100% of the RDA from iron-enriched rice. Apprehensions with regard to iron overload among healthy persons led the FNRI to redefine the objective of iron fortification in rice by providing a significant percentage of the RDA for iron but not significantly more than 100% for any age group. Thus, in the current iron-fortification programme, a fortification level of 6 mg of iron per gram of premix rice added to ordinary milled rice at a ratio of 1:200 (i.e., 5 g of premix to 1 kg of ordinary milled rice) is being maintained, thus providing each segment of the population with a significant proportion of the RDA for iron, as shown in [table 1](#).

The coating has also undergone reformulation in view of the ban on the use of some of the original ingredients. This has affected iron retention to some extent,

TABLE 1. Daily amount of iron provided to different population groups by fortified rice

Group	Iron (mg)	% RDA
Pre-school children	3.6	40.0
Schoolchildren	7.5	63.0
Adult men	13.5	113.0
Adult women	9.9	40.0
Pregnant women	10.5	26.0
Lactating women	11.4	50.0

particularly due to the loss of iron during the rinsing of rice grains prior to cooking. Initial estimates of iron losses after rinsing and cooking of enriched rice ranged from 11% to 45% in an ongoing study at FNRI [8].

The processing of the iron premix involves the following steps adapted from the Ricegrowers' Cooperative Limited:

1. The fortificant (FeSO_4) is prepared and mixed with the coating solution in a suspension tank;
2. The contents of the suspension tank are pumped into a rotating mixer;
3. The fortificant and coating solution are sprayed over rice kernels in the mixer;
4. The fortified rice grains are dried.

Studies

Field trials in Gen. Natividad, Nueva Ecija

Following the development of the technology by FNRI and during an Advocacy Forum to End Hidden Hunger in June 1993, Fidel V. Ramos, President of the Philippines, endorsed iron-fortified rice as a vehicle to control iron deficiency in the country. Also at the conference, the Secretary of Health, Dr. Juan Flavio, referred to enriched rice as FVRice (fortified vitamin rice), a generic term to indicate fortification with one or more of the micronutrients vitamin A, iron, and iodine. Thus, iron-fortified rice has come to be known as FVRice-iron. During the same forum, the governor of Nueva Ecija, a major rice-producing province in the Philippines, took up the challenge and invited the government to pilot the rice-fortification programme in his province. This led to the launching of the FVRice-Iron Programme during the province's foundation day on 3 September 1993.

As part of the launching of FVRice in Nueva Ecija, a field trial of FVRice-iron was carried out for six months in one nutritionally depressed municipality of Nueva Ecija. The trial involved 20 families in each of four barangays of Gen. Natividad, Nueva Ecija. The families were provided with a six-month supply of FVRice-iron rice premix with instructions on how to prepare the rice in the kitchen. The haemoglobin levels in pre-

school children were measured at baseline and at six months. The results showed a significant reduction in the prevalence of anaemia among the children, from 88.8% at baseline to 73.5% after consumption of the rice for six months. Mean haemoglobin at baseline (10.3 ± 1.6 g/dl) also increased significantly after three months of intervention (11.2 ± 1.4 g/dl).

Pilot test in 15 municipalities

In 1995 FVRice-iron rice premix was sold by the Nueva Ecija Grains Retailers Association in 5-g and 25-g sachets in 15 pilot municipalities. These municipalities were identified by the Provincial Health Office of Nueva Ecija as nutritionally depressed. A 5-g FVRice-iron rice premix sachet is intended to be mixed with 1 kg of ordinary rice, whereas the 25-g sachet will enrich 5 kg of rice. A social marketing and promotion campaign was jointly carried out by the private manufacturer of the FVRice-iron rice premix and the local nutrition committee of each municipality, together with the Nutrition Service of the Department of Health and the FNRI. In Gen. Natividad, Nueva Ecija, the women's group has actively taken part in selling FVRice-iron premix through the Socio-Economic Assistance component of the Barangay Integrated Development Approach for Nutrition Improvement (BIDANI).

Clinical trials of FVRice-iron in Dasmariñas, Cavite

In 1994 clinical trials of FVRice-iron were also carried out in a public elementary school to determine the effect of daily consumption for six months on the iron status of schoolchildren. The trials involved 173 elementary-school children 9 to 12 years of age, who were randomly assigned to the experimental and control (unfortified rice) groups. Iron-fortified rice was prepared using a 1:100 ratio of premix to rice, so that one serving of 100 g of rice contained more or less the amount of iron a child would obtain from one day's intake of iron-enriched rice prepared with premix and ordinary rice at a ratio of 1:200. The ratio should have been 1:50 or 1:75, but the noticeable greyish colour and distinct odour of the fortified rice were unacceptable. The iron-fortified rice used in the study thus provided 5.33 mg Fe/100 g or an average of 38% of the RDA. The rice was served daily during school days at lunch time.

After six months there was a significantly greater increase in haemoglobin among both boys and girls in the experimental group than among those in the control group (table 2). At the same time, there was a significant reduction in the proportion of children with haemoglobin deficiency, as well as an increase in the proportion of those with normal levels after consumption of iron-fortified rice an average of four to five days per week (taking into consideration the children's absences during the study period). There was also a sig-

TABLE 2. Mean increase in serum haemoglobin of children after six months of consuming iron-fortified or unfortified rice

Sex and age (yr)	Increase in serum haemoglobin—g/dl (N)	
	Unfortified rice	Iron-fortified rice
Males	0.8 ^a	1.0 ^a
9	1.0 (16)	0.9 (13)
10	0.7 (11)	0.9 ^a (12)
11	0.6 (6)	1.1 ^a (10)
12	—	—
Females	0.6 ^{a,b}	1.1 ^{a,b}
9	0.6 ^a (18)	1.0 ^a (18)
10	0.6 ^a (21)	1.0 ^a (15)
11	0.5 ^b (20)	1.5 ^{a,b} (11)
12	—	1.0 (2)
Total	0.6 ^{a,b}	1.0 ^{a,b}

a. $p \leq 0.01$ within study group.

b. $p \leq 0.01$ between study groups.

nificantly greater increase in the proportion of children with low to deficient serum ferritin in the control group than in the experimental group.

A logistic regression analysis revealed that the chance of improving iron status and reducing the prevalence of anaemia was 2.3 times higher among schoolchildren fed iron-fortified rice an average of four to five days a week than among those given unfortified rice. It is likely that a greater impact would have been achieved through daily intake of fortified rice in a predominantly anaemic population.

Bioavailability study

The bioavailability of iron from unfortified (meal A) and FVRice-iron-fortified (meal B) meals was determined by simultaneous determination of ⁵⁹Fe and ⁵⁵Fe in blood in 20 healthy human subjects. FVRice-iron was prepared by mixing 1 part of premix rice to 200 parts by weight of ordinary rice. The total iron content of the FVRice-iron alone (uncooked) was 5.71 mg/100 g, and 2.84 mg/100 g when given as a mixed diet. The geometric mean iron absorption from meal A was 6.88%, significantly higher than the 5.41% absorption from meal B. However, the amount of iron absorbed increased significantly from 0.30 to 0.40 mg ($p < 0.01$) when the total non-haem iron content was considered. Consumption of 120 to 150 g of rice daily might satisfy about 65% to 81% of the iron requirements for one- to three-year-old children, thus exceeding the goal of 40% to 50% of the RDA for this age group. Fortification of rice with iron in the form of ferrous sulphate seems to be effective, supplying an appropriate amount of absorbable iron.

Current status

A prototype machine for the production of iron premix with a capacity of 200 kg per batch has been developed for the rice-fortification programme by the FNRI. Moreover, the technology for the manufacture of the iron premix is currently being transferred to the Food Development Centre (FDC), an agency under the umbrella of the National Food Authority (NFA). At present, the FDC is preparing to pilot the mixing of premix rice in NFA's Valenzuela mill, which supplies NFA rice to metropolitan Manila.

To provide the basis for the design of social marketing strategies, research is currently being conducted in collaboration with the Nutrition Service of the Department of Health. Some findings from this research are already being implemented in the programme design.

Problems and constraints

Fortified foods are expected to cost more than unfortified foods. For iron-fortified rice, the added cost is estimated to be 2.5% more than the cost of unfortified rice. At the prevailing price of rice in the market today, this will add a minimum of 0.40 pesos (US\$0.02) to the price. Initial findings of the ongoing Formative Research on Fortified Foods, which includes rice, indicate that mothers may purchase fortified rice in spite of its higher cost if they are made to recognize the advantages. Since both fortified and unfortified rice will probably be available during the initial years of the rice-fortification programme once it is implemented, consumer demand will need to be strongly oriented towards the fortified product by well-tested marketing techniques.

As previously mentioned, rice milling in the Philippines is not centralized; there are numerous rice mills of varying capacities. Mandatory fortification will thus pose difficulties for enforcement. The requirement of additional equipment (e.g., precision feeders at the mills) may also pose a problem for smaller rice mills and perhaps even for larger ones as well.

Furthermore, home mixing in the kitchen will require the acquisition of skills in measuring and mixing. In focus-group discussions, the better-educated mothers expressed concern that this might be a problem for less-educated and illiterate mothers, who might have a greater need for fortified rice. The fortification of NFA rice, which is frequently consumed in lower-income households, addresses this concern to some extent. Nevertheless, education on proper measurement and mixing of iron premixes for home enrichment will need to be incorporated into social marketing and promotion activities.

Future prospects

It has been proposed that rice fortification in the Philippines will be implemented via mill enrichment and home enrichment. There are a number of rice mills in the country, many of them medium- to large-sized mills operated by the NFA, private or farmers' cooperatives, or private individuals.

The NFA, which caters to about 10% of the market, particularly in low-income groups in urban areas and fishing and other non-rice-producing villages, has agreed to make iron-fortified NFA rice available to all consumers throughout the nation. To reach the remaining 90% of the market, enrichment in private mills and mills operated by cooperatives will be encouraged.

For the home-enrichment programme, the iron

premix will be available through the usual retail system. This strategy is aimed at rural households and communities that may not have access to mill-enriched rice.

In addition to use in the household, iron-enriched rice, whether enriched at the mill or with an iron premix, will be distributed through the country's Food Assistance Programme and Disaster Relief Operations as well as through school cafeterias, hospitals, and other institutions.

It is hoped that it will not be necessary to enact legislation mandating fortification by rice millers unless the fortification programme teeters on the edge of failure for the second time. Legislation providing incentives to rice millers to fortify is nevertheless welcome. And with all these, advocacy and social marketing will play very vital roles.

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History of fortification of margarine with vitamin A in the Philippines

Florentino S. Solon

Abstract

The search for a suitable vehicle for vitamin A fortification in the Philippines led in 1991 to Star Margarine, a hydrogenated margarine product that had been popular in the country since 1931. The initial study to determine the stability of β -carotene and vitamin A (retinol palmitate) in the product showed high percentages of vitamin A retention and good thermal stability, as indicated by high vitamin A recovery after being heated. Later, a double-blind, randomized community trial to determine the effects of consumption of non-refrigerated vitamin A—fortified margarine on the vitamin A status of three- to six-year-old children also showed an increase in mean serum retinol in the experimental group and a decrease in the control group after six months of daily consumption of the product. The multiple adjusted increment over control was 2.4 $\mu\text{g}/\text{dl}$ ($p < .001$). The prevalence of low serum retinol ($< 20 \mu\text{g}/\text{dl}$) decreased from 25.7% to 10.1% in the experimental group but remained unchanged in controls (26.7% to 27.7%) ($p < .01$ at six months). Although its vitamin A content has been increased so that each serving of one tablespoon provides 100% of the recommended dietary allowance for Filipino young children, the marketed product has remained affordable to consumers and has been made more accessible by reducing container sizes. It has also received the Department of Health seal of recognition as a product that meets national fortification standards. The fortification of Star Margarine exemplifies the close collaboration of government and non-governmental organizations, industry, academics, and other sectors in confronting a public health problem.

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Mention of the names of firms and commercial products does not imply endorsement by the United Nations University.

Introduction

Vitamin A deficiency continues to be a public health problem in the Philippines, as evidenced by the 34% subclinical prevalence of the disorder. The vitamin A intake of the population is low in both urban and rural areas, and what vitamin A is consumed is mostly in the form of provitamin A carotenoids. This situation is further compounded by low fat intake and high prevalences of infections and parasitic infestations [1, 2].

The Philippine Plan of Action for Nutrition, a vital part of the government's Medium-Term Development Plan, addresses the malnutrition problem through five impact programmes: food security, micronutrient supplementation and food fortification, credit assistance for livelihood, nutrition education, and food assistance [3]. An interagency, multisectoral National Micronutrient Action Team was organized to formulate and implement the national micronutrient programme, including food fortification—the addition of essential micronutrients to processed foods. The National Micronutrient Action Team is assisted by the Vitamin A Expert Group, as well as expert groups on iron and iodine, supported by international agencies and local non-governmental organizations [4].

In announcing the government's micronutrient policies and programmes, the President met with food manufacturers and issued directives for the support of pertinent public institutions [5]. The policy is to fortify priority staple foods on the basis of national nutrition surveys. It specifies the fortification of salt with iodine; margarine, cooking oil, wheat flour, and sugar with vitamin A; and wheat flour and rice with iron [3, 4]. The recent national nutrition survey revealed that of 25 commonly consumed foods, 11 are potentially fortifiable, 7 of them with vitamin A: sugar, oil, bread, monosodium glutamate, soy sauce, milk, and rice [1].

Choosing a processed food to be fortified

Reflecting upon lessons learned more than two decades

ago during the fortification of monosodium glutamate with vitamin A in the Philippines, researchers chose margarine as the food to be fortified [6]. Margarine was fortified with vitamin A in Denmark as early as the 1930s, which reportedly contributed to the elimination of xerophthalmia.

Star Margarine, a product that does not require refrigeration, has been popular in the Philippines since 1931, before the advent of electricity in most parts of the country. The margarine is centrally produced and has high potential for wide consumption, especially by the poor or groups at high risk for vitamin A deficiency. A nationwide market survey conducted by the manufacturer in 1988 revealed that the margarine was consumed by a large majority (94%) of the population, 89% of whom had an annual income under 15,000 pesos (US\$1 = 38 pesos). Consumption was higher among people from rural areas than those from cities. The margarine was eaten mostly with bread (88%) and rice (28%), as well as being used for frying (23%), sauteeing (11%), and other cooking methods [7].

Advocacy and collaboration

In 1990 the dean of the Johns Hopkins University School of Hygiene and Public Health advocated the fortification of margarine with vitamin A by the Procter & Gamble Company in Cincinnati, Ohio, USA, when he learned about its Philippine product line Star Margarine. During a trip to Manila, the dean met with officials of the Philippine branch of Procter & Gamble to discuss the possibility of fortifying Star Margarine with vitamin A.

The manufacturer wanted to maintain its market dominance and to improve the nutrient content of the product further. Executives of the manufacturing firm met with officials of the Nutrition Centre of the Philippines to discuss collaboration in the fortification of the margarine.

Two options were raised during the discussion. The first one involved undertaking a quick feasibility study of increasing the amount of vitamin A in the margarine. Should the results of the study prove acceptable, the fortified margarine was to be launched immediately on the market. This option was initially favoured by the manufacturer.

The second option was to undertake a stability study and then a field trial to assess the effects of consumption of fortified margarine on the vitamin A status of pre-school children. This option, however, meant extending the study from six months to one year, with added financial and time constraints along the way. In spite of this fact, the second option was chosen. Both parties were convinced that a field trial could enhance the acceptability of the fortified margarine as beneficial to people's health, particularly those at risk of mi-

cronutrient deficiencies. Taking the second option resulted in a series of collaborative efforts between and among agencies in the Philippines and abroad. The manufacturer provided the necessary financial support, while the Nutrition Centre of the Philippines was the principal investigator in the field trial. Johns Hopkins University assisted in the research design of the field trial. The project was endorsed by the Philippine Department of Health.

Johns Hopkins also sent an expert in high-performance liquid chromatography to train the staff of the Department of Biochemistry at the University of the Philippines College of Medicine and the Food and Nutrition Research Institute to perform an in-country analysis of serum retinol. However, the Philippines was beset at that time by an energy crisis, and daily power failures occurred almost nationwide, which made it necessary to perform serum retinol analysis by high-performance liquid chromatography outside the Philippines. The analysis was eventually performed at the Institute of Nutrition at Mahidol University in Salaya, Thailand, and resulted in regional cooperation for biochemical analysis. The Department of Epidemiology and Biostatistics at the University of the Philippines College of Public Health conducted the statistical analysis and the interpretation of the results of the field trial.

Stability study

The vitamin A content of the margarine was increased by 300 µg retinol equivalents (RE) (from 131 to 431 µg RE) per serving (approximately 1 tablespoon, equivalent to 15 g), or about 115% of the recommended dietary allowance (RDA) for three- to six-year-old Filipino children. Each serving also contained 3 mg thiamine, 50 µg cholecalciferol, and 326 µg β-carotene as a colourant. The results of the stability study showed vitamin A retention to be 107%, 87%, and 58% after one, four, and eight months of storage under ambient conditions in the Philippines, respectively. The vitamin A recovery after heating the fresh margarine at 100°C for 5 minutes was 97%; the recovery was 83% when the margarine was cooked for 15 minutes at 177°C.

Field trial

A double-blind field trial was conducted by the Nutrition Centre of the Philippines to assess the effects of the consumption of vitamin A-fortified margarine on the vitamin A status of children three to six years of age in rural Cavite, Southern Luzon. The children of six villages were randomly assigned in a 2:1 ratio to groups receiving either vitamin A-fortified (experimental, $N=353$) or non-fortified (control, $N=350$) margarine (250 g/week, or ~2 tablespoons/child/day), con-

taining 431 μg RE (377 μg RE as retinyl palmitate and 54 μg RE as β -carotene) or 0 μg RE, respectively. The daily margarine intake per child was ~ 27 g in the experimental group and ~ 24 g in the control group [8].

After six months, the mean serum retinol had increased from 26.4 to 28.8 $\mu\text{g}/\text{dl}$ in the experimental group but had decreased from 26.6 to 25.1 $\mu\text{g}/\text{dl}$ among the controls ($p < .001$ at six months). The multiple adjusted increment over controls was 2.4 $\mu\text{g}/\text{dl}$ ($p < .001$). The prevalence of low serum retinol (< 20 $\mu\text{g}/\text{dl}$) decreased from 25.7% to 10.1% in the experimental group but remained unchanged in controls at 26.7% to 27.7% ($p < .01$ at six months) (fig. 1). In a follow-up assessment, no children from the experimental group had developed xerophthalmia, but 1.4% and 1.8% of the children in the control group developed night-blindness and Bitot's spots, respectively. The trial showed that consumption of vitamin A-fortified margarine significantly improved the vitamin A status of pre-school Filipino children [8].

Using the research results

Social marketing

In the course of the field trial, the manufacturer began a social marketing campaign emphasizing the importance of vitamin A to the human body. The information was disseminated through 30-second radio and television spots with no mention of the fortified margarine product. The publicity did mention, however,

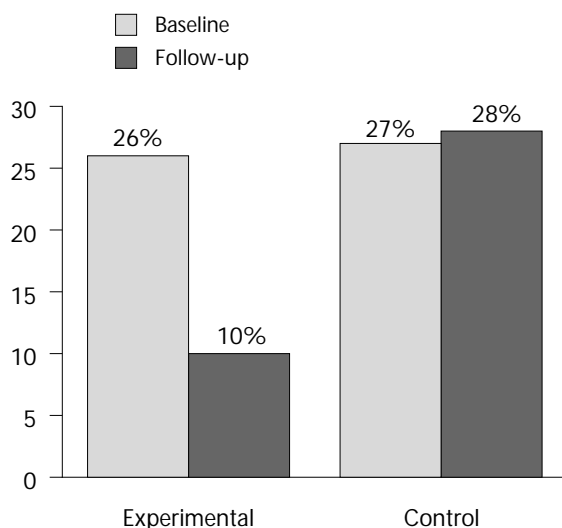


FIG. 1. Prevalence of low serum retinol among study children: proportion of pre-school children with serum retinol levels < 20 mg/dl at baseline (gray bars) and after six months (black bars) of consumption of vitamin A-fortified margarine (experimental) or non-fortified margarine (control)

that the messages were sponsored by the manufacturer and the Nutrition Centre of the Philippines.

Soon after the successful field trial, the manufacturer launched its improved, vitamin A-fortified margarine. At the same time, the manufacturer embarked on a full-scale multimedia campaign advertising the product. Three months after the market launching, sales of the fortified margarine had increased by about 20% over the same period in the preceding year [8].

The volume of production of Star Margarine in 1993, the first year of fortification, was 4 million kilograms [9]. In 1996, three years after the product's first appearance on the market, the volume of production increased to 5 million kilograms [10]. This substantial increase was evident despite the transition period brought about by the change in company ownership. The margarine brand is now owned by Philippine Dairy of the San Miguel Corporation, the largest food-manufacturing company in the country. The new owner took over the previous owner's commitment to maintain and strengthen the high-quality fortification standards of the margarine.

Affordability and accessibility to low-income groups

As a result of the field trial, the Nutrition Centre of the Philippines recommended that the manufacturer create an affordably priced pack of the fortified margarine for the benefit of low-income groups. The manufacturer developed the micro-nutripac, a 15-g package that held one serving of the fortified margarine containing 100% of the RDA for vitamin A and that sold for only US\$0.07. This enabled people from lower-income groups to buy a serving of the fortified margarine for as few as two people, paying only about 1% of a daily wage earner's disposable income for the day.

Recognition

The margarine was the first product in the Philippines to receive recognition for its high-quality fortification standards from the Department of Health. For the first time, a product was allowed to carry the Department of Health logo with the words "Accepted by the Department of Health" on the label. The label also stated in fine print, "The only margarine clinically tested by the Nutrition Centre of the Philippines." From this initial Department of Health stamp of approval evolved the Sangkap Pinoy seal, which has become the official mark of recognition for high-quality fortified food products. *Sangkap Pinoy*, which literally means "Filipino or indigenous ingredients," was the Department of Health's rallying cry in its campaign against micronutrient malnutrition. In fact, the observance of National Micronutrients Day was called *Araw ng Sangkap Pinoy*, or ASAP. Since Star Margarine first earned the Sangkap Pinoy seal, the government has undertaken a multi-

media campaign to generate awareness of the Sangkap Pinoy seal and its importance for promoting food fortification as a major strategy in the national nutrition programme. The Sangkap Pinoy seal is now placed on all fortified food products that meet the high fortification standards set by the government.

A processed food product that is awarded the Sangkap Pinoy seal may, however, lose the privilege of carrying it on its label if the product is found to be lacking in quality. The Department of Health's Bureau of Food and Drug Administration performs regular quality assurance tests to determine whether a product is still worthy of the seal. Despite these inspections, the Sangkap Pinoy seal is still vulnerable to abuse by food-manufacturing companies and advertising agencies. Products that are not staple foods, do not sell well, or are categorized as having "empty calories" can be conveniently fortified with a nutrient to qualify for a Sangkap Pinoy seal, which can then help increase sales. A trend towards the proliferation on the market of such processed food products dignified with a Sangkap Pinoy seal and preferred by consumers over more nutritious food items such as fresh milk and eggs is possible.

Assessment

No major problems were encountered in the fortification of the margarine, from its formulation with vitamin A, stability tests, and field trial to its full distribution through normal market channels. The technology is appropriate: vitamin A is soluble and stable in oil, even under storage and at high temperatures, and it is compatible with other nutrients such as vitamin B₁ and D₃. Above all, the vitamin A in the margarine is bioavailable and effective in improving the vitamin A status of young children. The additional cost of the fortificant is minimal: US\$0.01 per 100 g of margarine or about US\$0.001 per 15-g serving. These factors, including the fact that the manufacturer decided upon, initiated, and implemented the vitamin A forti-

fication, assure the sustainability of the effort.

Since the original fortification of margarine with vitamin A in the Philippines, five new brands of margarine have emerged on the market, all of them fortified with vitamin A although containing less than the level found in Star Margarine. A recent market survey conducted by the manufacturer showed that the consumption of Star Margarine among people with annual incomes under 15,000 pesos increased from 89% in 1988 to 91% in 1996. The consumption increased despite the presence of the five other margarine brands, which are priced lower than Star Margarine by as much as US\$0.03 to US\$0.08. However, the consumption of Star Margarine among people with annual incomes over 15,000 pesos decreased from 11% in 1988 to 9% in 1996 [7, 9].

The fortification of margarine with vitamin A shows that even in the absence of legislation or regulations, the manufacturer is capable of initiating the fortification of processed foods with micronutrients and sustaining the effort. Similar efforts by industry have also occurred in other parts of the world [11]. The manufacturer is actively supporting the Philippine Nutrition Programme by fortifying its margarine with vitamin A. In this regard, the manufacturer deserves some encouragement and incentives, which might be delivered in the form of support through strong national policy initiatives or an executive order from the President directing government institutions to help manufacturers undertaking fortification efforts so that the population's consumption of fortified foods is enhanced. In such cases, legislation may not be needed.

The fortification of Star Margarine with vitamin A is an example of how government and non-governmental organizations, industry, academics, and other sectors can work together and share skills and resources for the solution to public health problems. Advocacy efforts resulted in the cooperation of the food-manufacturing sector in allowing the use of its resources for the solution of a micronutrient-deficiency problem.

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Iron and micronutrients: Complementary food fortification

David L. Yeung

Abstract

Iron deficiency, one of the most prevalent problems of micronutrient malnutrition, occurs in both developing and industrialized countries. The impact of iron deficiency and iron-deficiency anaemia on the individual can result in lifelong disadvantages. The causes of the problem are many, but the principal cause is lack of iron-rich food. The International Conference of Nutrition sponsored by the World Health Organization (WHO) in Rome in 1992 estimated that over 2,000 million people worldwide suffer from anaemia, most of which is related to iron deficiency. Infants and young children are decidedly vulnerable groups, for a number of reasons. Their food choices are limited. The amount of food they consume is relatively low, but the demand for nutrients is high. Experience from industrialized countries indicates that one of the best strategies to eliminate or markedly reduce micronutrient malnutrition globally is through food fortification, with the goal of increasing the level of consumption of added nutrients to improve the nutritional status of the target population.

The current recommendation for infant feeding to ensure good iron status is breastfeeding for at least four to six months. The range of iron bioavailability in breastmilk is 50% to 80%, probably because of the presence of lactoferrin, which enhances iron absorption. Thus, it is not surprising that the prevalence of iron-deficiency anaemia in early infancy is inversely correlated with the incidence of breastfeeding. If breastfeeding is not possible, iron-fortified formula should be substituted. By about four to six months, an exogenous source of iron is required. The limited food choices and the few iron-rich foods generally available make fortification of complementary food mandatory. Iron-fortified cereal has been demonstrated to be one of the most effective food vehicles in combating

iron deficiency. It is usually the first solid introduced to infants to supplement breastmilk. Clinical research in China, Chile, and Canada has shown that the iron is bioavailable and the iron-fortified infant cereals are effective in the prevention and treatment of iron deficiency. In the United States the use of iron-fortified infant formula and cereal has significantly reduced iron deficiency among infants and pre-schoolers. Many other examples illustrate the importance of the food industry and food fortification in combating micronutrient malnutrition. The Global Plan of Action advocated collaboration among governments, non-governmental organizations, the private sector, local communities, etc. in the elimination of the problem. It is clear that without the food industry, iron-rich foods will not be available. Support and recognition of public health organizations must be given to the food industry to encourage the development of affordable and culturally appropriate iron-fortified foods.

Introduction

Infancy is a time of rapid physical growth as well as physiological, immunological, and mental development. During the first year of life, nutritional requirements are at their highest in the entire life cycle. Deficiency in energy or any of the essential nutrients can have dire consequences, some of which are long-lasting. In the first four to six months of life, the infant's nutritional requirements can be totally satisfied by breastmilk. Afterwards, complementary foods need to be introduced to augment energy and nutrient intake.

Complementary foods are, therefore, transitional foods consumed between the time when the diet is composed exclusively of mother's milk and the time when it is mostly made up of family foods. Complementary foods are consumed during the relatively short period from around 4 to 6 months to about 12 months of age. During the time they are consumed, complementary foods make up a large proportion of the baby's diet and contribute a significant amount of the nutrients that are necessary for growth and development.

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Mention of the names of firms and commercial products does not imply endorsement by the United Nations University.

The foods, therefore, must contain sufficient amounts of the essential nutrients to complement milk. Infants who do not receive enough complementary foods may be stunted or malnourished or both.

Among infants and pre-schoolers, the more prevalent forms of nutrient deficiencies are those of iron, vitamin A, iodine, protein-energy, riboflavin, calcium, and vitamin D. According to international agencies, millions of children suffer from deficiencies of iron, iodine, and vitamin A [1]. The incidence of these problems is markedly higher in developing countries; however, infants in industrialized countries are not spared. Iron deficiency has no borders, and in industrialized countries, approximately 15% of infants consume insufficient amounts of dietary iron [2].

Depending on the nutrient and the severity of deficiency, the consequences of malnutrition may include growth stunting, anorexia, susceptibility to infections, behavioural changes, and learning disabilities. The latter may have lifelong effects. For example, research has found that iodine deficiency [3] and iron-deficiency anaemia [4] during infancy can cause mental retardation or inferior psychomotor function in childhood, even after the deficiencies have been corrected. The causes of these problems are multifactorial and include poverty, ignorance, faulty feeding practices, infections and infestations, food scarcity, consumption of foods of low nutrient density, and low bioavailability of food nutrients. Here, the focus is primarily on the nutrient content and bioavailability of the nutrients in complementary foods.

Infants are particularly susceptible to nutrient deficiency, for a number of reasons. Their food choices are limited. The amount of food they consume is relatively low, but the demand for nutrients is high. By and large, the primary cause of undernutrition during infancy is a lack of suitable nutrient-dense complementary foods during the weaning period. The underlying reasons for this are many. Experience from industrialized countries shows that one of the best ways to ensure that infants consume all the essential nutrients in adequate amounts is to provide culturally acceptable foods that are affordable and fortified with the nutrients that are commonly missing in traditional diets. Indeed, one of the major strategies to eliminate or markedly reduce micronutrient malnutrition globally is through food fortification [5] (M. C. Cheney and N. S. Lee, personal communication, 1993). Fortification of complementary foods adheres to the following recognized principles: the food to be fortified is habitually accepted and consumed by the target population; the food is a suitable vehicle for the nutrient to be added; the nutrient is stable and bioavailable over the intended shelf life of the product; the amount of the nutrient added is biologically meaningful but not high enough to cause toxicity or adverse reactions; the organoleptic properties of the food are not altered in a negative way by the addition of the

nutrient; and the food is affordable by the target population [5-7]. The goal of food fortification is to increase the level of consumption of added nutrients to improve the nutritional status of the target population, which, in this case, is the infant population.

In industrialized countries the fortification of complementary foods is strictly regulated in terms of which foods are to be fortified, which nutrients are to be used as fortificants, and the minimum levels of the nutrients that may be added to a particular food. For example, juices may be fortified with vitamin C, and infant cereals are usually fortified with iron, calcium, phosphorus, thiamine, riboflavin, and niacin. Enrichment with protein is mandated, particularly if the cereal is not intended to be reconstituted with milk or formula. In certain situations, infant cereals may also be permitted to have added iodine, zinc, vitamin A, vitamin D, and other micronutrients. Meats, fruits, and vegetables are usually not fortified, although in the United Kingdom meat products for infants do contain added iron. In effect, if conditions require it, any food can be fortified with any nutrient, provided the principles of fortification are abided by and government regulations permit it.

In most societies nutrient-fortified cereals are the first complementary foods to be introduced to infants, sometime between four and six months of age. They are followed by vegetables, fruits, fruit juices, and meat products. By following this progression, a balanced diet containing all the essential nutrients can be achieved when the infant reaches eight to nine months. This dietary regimen obviates the need for nutrient supplements.

Iron deficiency is one of the most prevalent forms of malnutrition in the world. According to the report on Preventing Specific Micronutrient Deficiencies [1] of the 1992 International Conference on Nutrition (ICN) sponsored by the World Health Organization (WHO) in Rome, approximately 2,000 million people worldwide suffer from anaemia, mostly due to iron deficiency. The incidence of iron deficiency without anaemia is far greater than that of iron-deficiency anaemia. Virtually all countries are afflicted with the problem. The highest incidences occur in developing countries. The most afflicted groups, in descending order, are pregnant women, pre-school-age children, infants, other women, the elderly, school-age children, and adult men. The major causes of the problem are inadequate amounts of iron in the diet, low bioavailability of dietary iron, parasitic infestation, and excessive blood loss. In developing countries and in disadvantaged areas where the environment is unsanitary, all the above causes of iron deficiency may be present, whereas in industrialized countries where good health care is available, the main cause is a lack of sufficient amounts of available iron in the diet. This may be due to lack of foods rich in iron or poor food choice.

Iron is involved with a number of enzymes that are

required for oxygen metabolism; thus, iron deficiency has important health implications. Iron-deficiency anaemia reduces oxygen-carrying capacity and interferes with aerobic functions [8]. For older children and adults, it is well established that the work capacity and productivity of anaemic persons are much below those of non-anaemic persons [9]. Very severe anaemia is associated with increased mortality during childhood and pregnancy [10].

Recent research has shown that there is a relationship between iron nutritional status and cognitive development in young children [4]. Infants with iron-deficiency anaemia are easily fatigued, are more irritable, and have shorter attention spans. They also do less well in tests of psychomotor development during later childhood than those who were not iron-deficient in infancy. This effect is apparent even after the iron-deficiency anaemia has been reversed. The magnitude of the psychomotor deficit in childhood associated with iron-deficiency anaemia during infancy is approximately one standard deviation. However, iron deficiency without anaemia is not associated with psychomotor deficits. Thus, iron-deficiency anaemia during infancy may have long-term and irreversible adverse effects on cognitive development.

Iron deficiency has also been shown to increase the risk of childhood lead poisoning. Reports published in the United States showed that the prevalence of lead poisoning was three to four times higher among young children with iron deficiency than among children without iron deficiency [11]. There is evidence that the absorption of iron and other divalent metals such as lead and cadmium is more efficient in iron-deficient persons. Thus, preventing and controlling iron deficiency during infancy and early childhood has important public health implications as well as implications for national development.

The current recommendation to ensure good iron status is to breastfeed babies for at least four to six months, and longer if possible [12]. If breastfeeding is not possible or is terminated, the baby should be fed an iron-fortified infant formula until 9 to 12 months of age. At around 4 to 6 months, iron-fortified infant cereals are suggested [13]. This should be continued until the child reaches two years or more. Fruit juices should be given along with the infant cereal to enhance iron absorption. Cow's milk should be avoided until the infant reaches 9 to 12 months of age because it has a low iron content, interferes with iron absorption, and can cause microhaemorrhages in the small intestine [14].

Breastfeeding protects the young infant from iron deficiency. The level of iron in breastmilk is relatively low, but its bioavailability is in the range of 50% to 80%, probably because of the presence of lactoferrin, which enhances iron absorption. Exclusively breastfed infants have been shown to receive sufficient iron to sustain normal status until at least four to six months

of age [15]. Thus, it is not surprising that the prevalence of iron-deficiency anaemia in early infancy is inversely correlated with the incidence of breastfeeding, i.e., the higher the incidence of breastfeeding, the lower is the incidence of iron deficiency.

Cereals are usually the first solid foods given to infants, because they are readily available and culturally acceptable staple foods. They are introduced to infants at around four to six months to supplement breastmilk [16]. It has been demonstrated that the addition of nutrients to cereals and cereal products is one of the most effective ways of combating nutrient deficiencies. In many countries, commercially prepared infant cereals are fortified with iron, and their wide consumption has contributed to lower incidences of iron deficiency. A number of forms of iron are recommended for use [7]. However, the final choice depends on the availability of food-grade iron, the reliability of the supply, and compatibility with the process. In the past sodium iron pyrophosphate was used, which has since been found to be of low or variable bioavailability [17, 18]. Since 1972 it has been replaced by electrolytically reduced iron of small particle size that was deemed to be bioavailable.

In 1987 the bioavailability of electrolytically reduced iron was questioned [19]. Short-term feeding studies using natural isotopes did not resolve the question. Furthermore, studies of persons with good iron status tend to underestimate bioavailability. Subsequently, large-scale clinical studies were conducted in Chile [19] and Canada [20]. In both studies, normal and regular consumption of infant cereals fortified with electrolytically reduced iron was found to be efficacious in preventing iron deficiency.

The study in Canada was conducted to determine whether electrolytically reduced iron added to infant cereals was actually available for utilization by infants between 6 and 12 months of age. A six-month, double-blind trial involved 110 healthy term infants. All the infants were well-nourished and had good iron status. One group received 25 g per day of infant cereals containing 30 mg of added iron per 100 g. The control group received the same amount of non-fortified cereals. Other iron supplements were not included. Blood was collected monthly by fingerprick from each infant for determination of serum ferritin and haemoglobin. If ferritin fell below 10 µg/L, a putative end point was declared. Anthropometric measurements were performed to monitor growth of the infants.

At the completion of the study, the parents were offered a one-month supply of an iron supplement providing 8 mg of iron as ferrous sulphate per day. The parents were also asked to allow an additional blood sample to be taken at the end of the one-month period. The purpose was to assess iron storage in the two groups of infants. The extended study included 91 of the 110 infants. The results showed that significantly

fewer infants given iron-fortified cereal were at risk of reaching low haemoglobin values at the end of the six-month trial period than controls. Furthermore, the infants who received iron-fortified cereal had lower haemoglobin and serum ferritin responses to the ferrous sulphate supplement than controls. Thus, the infants who received iron-fortified cereal had better iron status and greater iron storage than those who did not. This study confirms the efficacy of iron-fortified infant cereals in reducing the risk of iron deficiency. Indirectly, the results show that the iron is bioavailable. Since the infants had good iron status at the start of the trial, the study tested the utilization of the fortification of the iron under the most challenging conditions. Two recent studies in Chile [19] and Canada (G H. Beaton et al., personal communication, 1995) confirm the results of earlier studies in Canada [20] and China [21] showing that infant cereals fortified with electrolytically reduced iron and ferric ammonium citrate, respectively, were efficacious in reducing iron deficiency.

There is also evidence that wide usage of cereals is effective in preventing iron deficiency in a population. For example, a study in Canada showed that close to 96% of infants aged 4 to 10 months were customarily given the cereals, and that the cereals were clearly the main source of iron in the infants' diets [22]. It was apparent that the recommended dietary allowance for iron could not be met without the presence of iron-fortified infant cereals in the diet.

Further proof that iron-fortified infant cereals are effective in reducing iron deficiency was provided in a report of the Women, Infants and Children (WIC) Programme [2, 23]. Regular consumption of iron-fortified infant formula and cereals by infants from disadvantaged families resulted in improved haematological indices of iron nutriture. Families in the WIC Programme were routinely provided with coupons for redemption of iron-fortified formula and cereal and vitamin C-fortified juice. Dietary assessment showed that these food items were indeed given to infants. Thus, the decline in the prevalence of iron deficiency in North America is attributable, in part, to the addition of a

bioavailable form of iron in infant cereals and the widespread use of the cereals.

Experience in North America showed that the effectiveness of iron fortification of infant formula and infant cereals in reducing the incidence of iron deficiency was due to a number of important factors. Past social marketing had instilled wide awareness of iron-fortified foods. The forms of iron added are efficacious and the products are culturally acceptable and affordable. The use of iron-fortified infant formula and cereals is advocated by health professionals in accordance with recommendations of authoritative organizations, such as paediatrics and dietetics associations.

In summary, micronutrient malnutrition among infants and pre-schoolers remains a concern in many parts of the world. The causes are multifactorial. Nevertheless, the problems can be successfully managed if there is multisectoral collaboration. Food fortification of complementary foods is one solution. For this to be effective, the nutrients to be used as fortificants and the vehicles to which the nutrients are to be added must be clearly identified. Furthermore, the compatibility of the fortification system needs to be established, as outlined by WHO. Of importance is the clinical evaluation of the efficacy or bioavailability of the nutrient in the food vehicle. Population studies of the effectiveness of the fortification programme also need to be conducted. One area that has not been elaborated upon is the importance of nutrition education and appropriate product promotion and labelling with proper instructions for safe use; these are required to generate awareness of micronutrient-deficiency problems and to encourage use of the products by the target populations. Although emphasis has been placed on iron fortification here, the same principles and procedures should be followed for the fortification of complementary foods with other nutrients. Multisectoral collaboration, as exemplified in certain industrialized countries, can eliminate or at least drastically reduce micronutrient malnutrition among infants and pre-schoolers in developing countries in the not-too-distant future.

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Triple fortification of instant noodles in Thailand

Visith Chavasit and Kraisid Tontisirin

Abstract

Because Thailand was facing problems with deficiencies of iodine, iron, and vitamin A, in 1994 a committee of the Ministry of Public Health proposed a feasibility study of fortification of instant noodle seasoning powder. This project was undertaken by universities, government, and the private sector. Micronutrient dosages per serving were set at 5 mg for iron, 50 µg for iodine, and 267 µg for vitamin A, all of which represent one-third of the Thai recommended daily intake (RDI). The results showed that a premix containing potassium iodide, encapsulated reduced iron, and vitamin A remained stable under accelerated storage conditions, with no adverse effects on the sensory qualities of most products. Information concerning the fortified nutrients as well as the types and brands of the fortified product was publicized through the media with support from manufacturers of instant noodles and a ministerial committee. The products were marketed at the end of 1996.

Introduction

Although protein–energy malnutrition in Thailand has lessened in severity over the past 10 years, deficiencies of certain micronutrients, such as iodine, iron, and vitamin A, are still significant. Among the many control and prevention strategies that have been implemented, fortification of industrially processed foods is now emerging as potentially important, since a growing reliance on such foods by the Thai people has arisen due to the country's rapidly expanding industrialized and cash-based market economy [1]. One such food is the instant noodle, which is acceptable, available, and affordable in Thailand.

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Mention of the names of firms and commercial products does not imply endorsement by the United Nations University.

Micronutrient-deficiency problems in Thailand

Micronutrient deficiency in a nation can take a heavy toll in lost productivity, vitality, and initiative. In Thailand iodine-deficiency disorders affect many people as a result of increasing deforestation and topsoil erosion. In 1995 about 6% of primary-school children were afflicted with goitre. The prevalence in the north was about 8%, the highest in the country, and reached as high as 28% in some provinces. The prevalence among primary-school children in other parts of the country was 2% to 7% [2]. To combat the problem in endemic areas, potassium iodate solution has been added to household, community, and school drinking water supplies for many years. Since 1994 table salt has been fortified with 50 ppm of potassium iodate or potassium iodide. However, community-produced salt, which is normally consumed by the target population, usually cannot be fortified to such a standard because of a lack of technology and low-quality salt. Despite these efforts, iodine-deficiency disorders persist as a significant public health problem.

Iron deficiency is found mostly in children and pregnant women. In the past, a high prevalence was correlated with hookworm infestation among people in southern Thailand. However, the problem is now widespread in all areas of the country. A 1991 survey indicated that the prevalence of anaemia in pre-school children ranged from 12% to 22%. In 1995 anaemia in primary-school children in all parts of the country ranged from 12% to 20%, while in pregnant mothers it ranged from 9% to 17% [3]. Currently, iron tablets are provided to pregnant women, although the impact of this supplementation is limited because of poor compliance and increased consumption of iron-rich foods by children.

The World Health Organization (WHO) does not classify Thailand as a country in which vitamin A deficiency is a public health problem. However, subclinical cases are sporadically found in many rural areas. In 1995 the prevalence of moderate subclinical vita-

min A deficiency in pre-school children was estimated at about 20%, as demonstrated by inadequate liver stores of vitamin A and low serum retinol levels [4]. This situation has improved since 1992, when the prevalences of active xerophthalmia, inadequate liver stores of vitamin A, and low serum retinol in southern Thailand were as high as 43%, 56%, and 11%, respectively [5]. This improvement is the combined result of a vitamin A capsule supplementation programme, increased production and consumption of vitamin A-rich foods, and a 1994 government regulation requiring the fortification of sweetened condensed milk, which is sometimes used as a substitute for breastmilk or infant formula by the poor, with vitamin A (330 mg retinol/100 g milk).

Government–industry–academic partnership

Based on the 1992 World Declaration and Plan of Action for Nutrition developed at the International Conference on Nutrition (ICN) in Rome, Thailand's Ministry of Public Health appointed an advisory working committee in 1993 to increase cooperation between government and the private sector in solving food and nutrition problems in the country. The committee was composed of representatives from the Ministry of Public Health, Ministry of Agriculture and Cooperatives, Federation of Thai Industries, and Institute of Nutrition of Mahidol University. The committee members agreed that cooperation among government, industry, and academia was necessary because it was impossible for the government sector alone to solve the nation's nutritional problems. It was also decided that the primary commitment of the committee should be solving micronutrient-deficiency problems, and that fortification of an industrially processed food with micronutrients should be pursued.

Instant noodle market in Thailand

Instant noodles sold in ready-to-prepare packages are a popular industrially processed food in Thailand. Six million packages are produced each day, 80% of which are made by only three companies. Most are consumed domestically, although they are also exported. In 1993 instant noodle consumption in Thailand was 30 packs per capita [6]. Over 90% of these instant noodles are of the deep-fried type, which are sometimes classified by academics as "junk food" due to their high salt, fat, and carbohydrate content and low-quality protein. Therefore, the label on the package suggests adding meat or egg and vegetables, which is the traditional mode of eating noodles in Thailand. However, because of inconvenience, this suggestion is seldom practised by consumers.

Both males and females aged 15 to 49 years from all

socio-economic strata in Thailand consume instant noodles. The consumption of the products according to the country's regions and zones is shown in [table 1](#). Forty-one percent of the products are consumed in Bangkok, at the same percentages as in up-country rural areas.

The cost of a 55-g package of instant noodles is only 3.50 to 4.00 baht (US\$0.14–0.16), whereas one serving of Thai fast food costs at least 10–15 baht (US\$ 0.50–0.60). This price increased in October 1996 after remaining at about 3.00 baht (US\$0.12) for almost 16 years. The price was previously fixed because of high market competition. Instant noodles are a low-profit-margin product, but they can be distributed to consumers all over the country. In addition to its low price, the product has acceptable sensory characteristics and good shelf stability. Instant noodles of various flavours are available in both original Chinese and traditional Thai styles. The shelf life of instant noodles is at least six months at room temperature. The product is widely accepted throughout the country and has become of interest as a vehicle for nutrient fortification.

Feasibility study of triple fortification of instant noodles

In late 1994 the ministerial committee agreed that a study of the feasibility of triple fortification of instant noodles should be undertaken. The committee and the manufacturers of instant noodles agreed to fortify the seasoning packet, because the seasoning powder does not need much additional cooking before consumption and is well protected in a separate bag within the package. To attract public interest in the project, the committee planned to include the fortification programme as part of the celebration of the golden jubilee of King Bhumipol's accession to the throne.

TABLE 1. Regional and zonal percent distributions of instant noodles

Location	Percentage
<i>Regions</i>	
Bangkok	41
Central	17
North 18	
North-East	18
South 7	
<i>Zones</i>	
Bangkok	41
Rest of country	
Urban	18
Rural	41

Source: Thai President Foods Public Company Limited, Bangkok, Thailand, 1996.

However, this would have set the deadline for launching the product at December 1996. The fortification dosages for iodine, iron, and vitamin A were 50 µg, 5 mg, and 267 µg, respectively, which represent one-third of the Thai recommended dietary intake (RDI) for these nutrients. This project has been conducted on a voluntary basis, and representatives from the manufacturers are working jointly with the committee members. For the feasibility study, information about the fortified products, such as the fortificant to be used, sensory acceptability, cost, and shelf stability, was evaluated.

Selection of the fortificants

A premix of potassium iodide, ferrous fumarate, and vitamin A palmitate was initially tested in several flavours of instant noodles. The manufacturers found that some seasoning ingredients containing Chinese five-spice powder, especially nutmeg, reacted adversely with ferrous fumarate, resulting in an unacceptably black-coloured soup. Iron EDTA was also tested, with the same result. Finally, encapsulated iron, which is a reduced iron encapsulated with partially hydrogenated oil as the coating material, did not react with those spices or with any other seasoning powders. Therefore, the premix used for fortification contained potassium iodide, encapsulated iron, and vitamin A palmitate. The premix was used at 20 mg per package of instant noodles.

Sensory acceptability

After the premix was selected, a sensory discrimination test was conducted using pork-flavoured instant noodles. Because this product has the mildest flavour of all the noodles, any off flavour caused by the fortificant could be easily detected. Results from the triangle test showed no significant difference in sensory qualities ($p > .05$) between the original and fortified products. For colour changes due to the reaction between certain seasoning powders and the iron fortificant, a study was performed by observing colour changes in cooked *Pa-Lo* duck-flavoured instant noodles that contain Chinese five-spice powder. Observations of both normal and fortified noodles were made every 5 minutes for 30 minutes using a Munsell colour chart (Macbeth Division, Kollmorgen Instruments, Baltimore, Md, USA). This period is long enough for the average consumer to eat a bowl of noodles.

Cost

The premix increases the cost of the product. However, until 1999 the cost of the premix per serving of instant noodles will remain below 0.02 baht (US\$0.08). This cost has actually been lowered due to the special taxation rate for the premix, which was reduced from 45% to 10% at the request of the Ministry of Public

Health and a nutrient importer. Although the cost of fortifying instant noodles is not high, most manufacturers hesitated to join the programme at the beginning because of the low profit margin. Since October 1996, however, the manufacturers have raised their prices by 15% to 20%, which has eased the cost problem for many manufacturers. After encouragement from the Federation of Thai Industries, seven manufacturers of instant noodles agreed to join the project.

Shelf stability

A study of the fortified product's shelf stability was performed jointly by the manufacturers and the Institute of Nutrition at Mahidol University. The manufacturers prepared and packed fortified seasoning powders in their laboratories and incubated them along with unfortified seasonings under their own acceleration conditions. The results showed that most fortified seasoning powders had a shelf life of about three months, mainly on the basis of appearance criteria (as decided by each manufacturer). Some manufacturers found that the fortificants, especially iron, caused changes in the colour of dried onions and in the flavour of some of their products during incubation. Although this shelf life is acceptable to many manufacturers, it has caused uncertainty among some whose products need to be on the market for more than three months. The incubated seasoning powder from each period was later analysed for its content of fortified micronutrients at the Institute of Nutrition. The results showed that the fortified micronutrients were stable under the accelerated incubation conditions. However, a non-homogeneity problem was found in some sample sets, since they were prepared on a small scale without using a standard mixing machine. From this study, the committee suggested to the Food and Drug Administration that the standard for the fortification dosage might need an allowance of 20% for overage.

Preparation stage before product distribution

A strategy for launching the product was carefully designed to assure fairness in terms of marketing and convenience in terms of regulations for all participating manufacturers. However, consumers must receive correct information and have access to high-quality fortified products at an affordable price. The following processes were performed in order to prepare for distribution.

Registration and labelling

The Thai Food and Drug Administration eased the registration process for new fortified products for manu-

facturers of instant noodles. The manufacturers were allowed to use the results of the feasibility study from the Institute of Nutrition instead of analysing each product. The Thai Food and Drug Administration and the committee also established standard terms to be used on the labels of fortified products: "Fortified with iodine, iron, and vitamin A" on the front panel and "contains iodine, iron, and vitamin A in amounts that fulfil $\frac{1}{3}$ of the Thai RDI" in the ingredient list. The manufacturer was allowed to use these terminologies without having to apply for a new label.

Public relations, advertising, and marketing

The committee organized three press conferences to release information about the project through newspapers, radio, and television. Conferences were held about the agreement with the manufacturers before and after introducing the product. Based on their market shares, the manufacturers also proportionally provided funds for advertising the project and the fortified brands. Advertising posters were also sent to sub-district health centres and even lower levels by the Ministry of Public Health. In addition, the Ministry of Public Health provided another marketing channel for the manufacturers by allowing them to send the fortified products through the health service system at the village level.

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Post-marketing activities

After the fortified products are introduced on the market, the fortification dosage of the products from each factory and the stability of each fortificant under real distribution conditions will be closely monitored. If necessary, academic advice, further research, or even law enforcement may be implemented. The percentage allowance of the fortification dosage also must be reconsidered. A short-term metabolic study or field efficacy trial of the bioavailability of these fortificants in the target population should be conducted in order to confirm their benefits. Studies of long-term community effectiveness should be performed to evaluate the cost-effectiveness of this programme.

Conclusion

Successful cooperation among the government, academia, and the industrial sectors can result in a "win-win situation," in which every party can benefit. The fortification of instant noodles is only an example of such cooperation. It is to be expected that difficulties will arise during operation of the programme, especially when the project is performed on a voluntary basis. However, once it is sustainable, the consumers will benefit the most.

Multiple fortification of beverages

Denis Barclay

Abstract

Diet-related micronutrient deficiencies rarely occur in isolation; deficiencies of iodine and vitamin A or of iron and vitamin A or zinc are often observed in the same populations. In addition, widespread deficiencies of some micronutrients, for example, zinc and calcium, may often go undiagnosed because of the absence of specific and sensitive status indicators. Multiple micronutrient supplementation can be more effective in improving nutritional status than supplementation with single key micronutrients; therefore, the multiple fortification of appropriate food vectors, including beverages, is of interest from the nutritional standpoint.

Beverages fortified with multiple micronutrients include dairy products, chocolate beverages, fruit juices, and soya-based drinks. As well as the documented or estimated micronutrient deficiencies and the requirements of the target population or consumer group, the conception of such a multiply fortified beverage must take into account a number of other important factors. The choice of the chemical form of the fortification micronutrients should be made with consideration of bioavailability, the effects on the organoleptic characteristics of the particular beverage, and cost. The initial calculation of the composition of the micronutrient premix should include the levels of micronutrients in the raw materials used and the estimated losses of specific micronutrients during processing and storage. Preliminary production and storage trials are then needed to determine the actual losses. The composition of the micronutrient premix may then be finalized. Interactions, both positive and negative, between fortification micronutrients may also need to be considered. For example, the bioavailability of iron may be enhanced by the addition of vitamin C, whereas mineral-vitamin and vitamin-vitamin interactions can accelerate the destruction of some vitamins.

To render quality control procedures simple and cost-effective, only a limited number of fortification micronutrients, which are especially sensitive to losses and which are easy to measure, may be analysed. Simple, inexpensive, and rigorous analytical methods for such measurements are now available.

Introduction

The food category of beverages encompasses a wide range of products, including fruit juices and drinks, milks and milk drinks, chocolate (malt) beverages, instant flavoured drinks, nectars, meal replacers, supplements for pregnancy and lactation, sports drinks, and others. Micronutrient-fortified foods, including beverages, are becoming increasingly popular in many countries. In a recent survey in the United States, more than half of the respondents reported consuming micronutrient-fortified fruit juices or drinks several times weekly [1]. The contribution to micronutrient intakes from fortified foods in the United States ranged from 6% for vitamin B₆ and folic acid up to 24% for iron and vitamin B₁ [2].

Rationale for multiple fortification

Nearly all fortified processed foods contain more than one added micronutrient. Milk products are often fortified with vitamins A and D only, whereas other beverages are often fortified with many minerals and vitamins. Multiple fortification of different types of beverages can be justified for a number of reasons. Virtually all broad-based nutrition surveys show that individual micronutrient deficiencies rarely occur in isolation. Since many major foods are excellent sources of several micronutrients, inappropriate food choices and economic constraints leading to unbalanced diets are unlikely to provide adequate levels of all micronutrients.

The existence and extent of the deficiencies of some micronutrients remain largely unknown, partly because

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Mention of the names of firms and commercial products does not imply endorsement by the United Nations University.

of lack of adequate survey data, but also largely because of the absence of easily measurable, sensitive, and specific indicators of micronutrient status. Although the existence of such status indicators has allowed estimation of the dimension of deficiencies of iron, vitamin A, and iodine, this is not the case for other key micronutrients, such as zinc and calcium. Deficiencies of these two minerals may be as widespread and as costly in terms of human health and well-being as the better-documented deficiencies of iron, vitamin A, and iodine.

Finally, multiple micronutrient supplementation has been shown to have a greater impact on nutritional status than administration of the supposed key deficient single micronutrient. For example, a 10-week, double-blind study on zinc and growth in six- and seven-year-old Chinese children showed that multiple micronutrient supplementation resulted in greater improvement in linear growth than zinc supplementation alone [3].

Appropriate fortification

Although there are several good arguments in favour of multiple fortification, a number of factors must be taken into account before deciding on the fortification of a particular food product. Obviously, the food vector, the fortification micronutrients, and their levels must be chosen as a function of the nutritional requirements and deficiencies as well as of the dietary habits of the target population or consumer group. As a general rule, and in order to provide nutritionally appropriate amounts of micronutrients without creating excess or imbalance, one portion of the food should not provide too large a proportion of the requirements of the target consumer.

Vitamin stability

The stability of vitamins is affected by a number of factors, such as temperature, moisture, oxygen, light, pH, minerals (especially iron and copper), vitamin-vitamin interactions, and other food components [4]. Vitamin stability is affected most by heat, moisture, pH, and light, but given their chemical heterogeneity, vitamin losses in different foods vary considerably during both processing and storage of the final product [5]. The most unstable vitamins are C, A, D, B₁, and B₁₂. Because of their multiple oxidation states, the presence of metal ions (iron and copper) accelerates degradation of vitamins, especially vitamins C, A, and B₁. Fortification with several vitamins may give rise to vitamin-vitamin interactions that may accelerate the rate of breakdown of some vitamins; the best-known interactions are those among vitamins C, B₁, B₂, B₁₂, and folic acid [6]. The extent of these interactions is also dependent on the nature of the food product as well

as on temperature, moisture level, pH, light, etc. during processing and storage.

Therefore, to maintain the micronutrient levels declared on the product label throughout a product's shelf life, the amount of vitamins added during processing needs to be higher than the levels reported on the label. The difference between the declared and formulated vitamin levels, termed "overage," will be different for each food application. Vitamin overages are normally calculated as a percentage of the declared level: $\text{Overage} = (\text{formulated vitamin level} - \text{declared level}) / \text{declared level} \times 100$.

For a milk-based drink powder fortified by dry mixing, the overages range from 10% for vitamin E and niacin up to 25% to 30% for vitamins C, A, and D [6]. For liquid beverages stored in cans, the overages may be as high as 100% for vitamin C and other sensitive vitamins.

Micronutrient bioavailability and organoleptic quality of fortified foods

The nature of the food or beverage vector will have considerable bearing on the fortification, since organoleptic alterations caused by certain added micronutrients must be dealt with quite often. The bioavailability of added micronutrients, especially minerals and trace elements, must also be taken into consideration. In these two respects, iron is undoubtedly the most difficult micronutrient to add to a food, yet iron deficiency is the most widespread micronutrient deficiency in the world today. The choice of an iron-fortification compound depends primarily on the nature of the food itself, and is nearly always a compromise between maximal bioavailability and minimal organoleptic alteration [7]. Soluble iron compounds such as ferrous sulphate are very well absorbed but can give rise to unacceptable colour and taste changes in some products. For example, many milk products are satisfactorily fortified with ferrous sulphate, whereas its use in other foods containing easily oxidizable unsaturated fatty acids leads to rancidity or to colour changes in polyphenol-containing beverages such as cocoa drinks [8]. In many cases, it is possible to improve the bioavailability of iron from foods by the addition of an appropriate amount of ascorbic acid. A molar ratio of ascorbic acid to iron of 2:1 often significantly enhances iron absorption [9], but the optimal ratio depends on the nature of the food or beverage, and especially on the levels of other enhancers and inhibitors of iron absorption in the product.

Mineral interactions and bioavailability

Interactions between minerals can also have implications for mineral bioavailability in multiply fortified products.

Iron, zinc, and calcium have been the most studied in this respect [10]. For example, in the absence of phytic acid, the effect of calcium on zinc absorption is low. However, when phytic acid is present, calcium significantly inhibits zinc absorption. Likewise, oral iron supplements significantly inhibit inorganic zinc retention when consumed simultaneously at iron-to-zinc ratios as low as 1:1 [11, 12]. To determine the nutritional relevance of this interaction in food, zinc bioavailability studies were carried out in human adults using food-fortification levels of iron and zinc that are typical in infant cereals and formulas [13]. The results showed that normal levels of iron fortification do not diminish zinc absorption. This has also been confirmed in infants [14].

Another extensively studied interaction is that between calcium and iron. A number of single-meal studies have shown that calcium does have an inhibitory effect on iron absorption. For example, Hallberg et al. [15] showed that 165 mg of calcium given as milk reduced iron absorption by as much as 50% to 60%. Recently however, the “acute” single-meal approach has been questioned as exaggerating the effects of food inhibitors and enhancers of iron absorption. This has led to “whole-diet” absorption studies in order to evaluate the longer-term effects of inhibitors and enhancers of iron absorption. These studies showed that the strong effects of enhancers and inhibitors on iron absorption observed in acute studies were generally much lower in whole-diet studies [16-18]. Moreover, in a recent chronic dietary labelling study, in which the effects of inhibitors and enhancers were studied on an even longer-term basis of several weeks, Reddy and Cook [19] did not observe any significant inhibitory effect of dietary calcium on iron absorption nor any enhancing effect of vitamin C. The only dietary components shown by multiple regression techniques to influence iron absorption were meat (enhancing) and polyphenols (inhibiting). It is very likely, therefore, that in varied, adult Western diets, the effects of individual enhancers and inhibitors of iron absorption are of much less nutritional significance than has been suggested by single-meal studies. This remains to be shown for typical diets in other regions of the world. Even if in the long term there is a low to mild inhibition by calcium of iron absorption from iron-fortified milk beverages or from calcium- and iron-fortified beverages, the iron will still be absorbed to an appreciable extent and will, therefore, be of benefit to those consumers whose dietary iron intake is inadequate. Such beverages can provide nutritionally relevant amounts of iron.

Designing micronutrient premixes

Once the appropriate beverage for fortification has been identified, the next step is to design the micronutrient premix(es), as a function of the:

- » micronutrient requirements and status of the target consumer,
- » micronutrient levels in the raw materials to be used,
- » estimated processing and storage losses (as above),
- » expected homogeneity of mixing.

For fortifying with both minerals and vitamins, two premixes are generally used, one for minerals and another for vitamins, in order to minimize metal-catalysed degradation of vitamins during storage of the premix. Usually, a small quantity of the premixes is obtained from micronutrient suppliers for preliminary, small-scale production trials. Complete micronutrient analyses of these trial products are then carried out to calculate the final specifications of the premixes.

Quality control in food fortification

Fortification of staple or processed foods requires properly designed and resourced quality control systems. Neither government legislation nor industrial specifications for food fortification will be effective without adequate quality control, both at the production site and in central laboratories. Reliable quality control of the addition of micronutrients to foods can only be obtained by the careful use of appropriate and validated analytical techniques in the hands of trained analysts. Validation of analytical methods involves the establishment of performance characteristics such as specificity, sensitivity, working concentration range, limit of detection, limit of quantitation, ruggedness, accuracy, and precision.

In order to ensure that the mineral-trace element premix is added to a processed food at the correct level, iron is often used as a tracer. Several methods can be used for iron determination: X-ray fluorescence spectroscopy, which is rapid (10 minutes) and can be used on production lines; atomic absorption spectroscopy, which is the reference method and is generally used in quality control laboratories (2 hours); inductively coupled plasma emission spectrometry (2 hours); and calorimetric methods (rapid test kit, 20 minutes).

The repeatability of the different methods varies from 5% to 10%, whereas the reproducibility varies from 10% to 20%. The method used depends on the available laboratory resources as well as on the desired precision. Quality control data on the addition of trace elements to milk powder by dry mixing show that iron determination alone allows for control of the addition of the trace element premix.

Similarly, the addition of vitamins to foods in a multivitamin premix may be controlled by determination of vitamin C as the tracer in the food, since it is often the most sensitive to degradation. Methods commonly used include high-performance liquid chromatography, titrimetry using a visual or calorimetric end point, or rapid calorimetry (Merck RQ Flex, Darmstadt, Ger-

many). The latter method may be used on production lines to ensure the presence of the premix in the product. High-performance liquid chromatography and titrimetry are used in quality control laboratories and have better repeatability than the rapid method. Again, quality control data on the stability of vitamins A, C, and D show that determination of vitamin C only can be used to check the levels of the vitamins in the product during prolonged storage.

Summary

The numbers and types of fortified beverages are ever-increasing and include milk and milk drinks, chocolate (malt) beverages, meal replacers, slimming beverages, sports beverages, supplements for pregnancy and

lactation, cereal drinks (cereal "milks"), fruit juices, and others. To have an appropriate impact on consumer health and nutrition, the development of such fortified beverages must be based on the dietary habits and nutritional requirements and status of the target consumer. The chemical form of the fortification micronutrients must be chosen to have maximal bioavailability while not producing unacceptable organoleptic changes. At normal fortification levels, mineral interactions generally do not lead to nutritionally significant decreases in mineral bioavailability. Micronutrient losses during processing and storage, especially losses of certain vitamins, must be quantified in order to determine the composition of vitamin and mineral premixes. Finally, effective fortification of foods and beverages can only be achieved if there is an appropriate quality control system.

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Fortification of salt with iodine

Junshi Chen and Huiyun Wu

Abstract

Iodized salt is the best means of providing iodine to deficient populations, and it has been used successfully and safely for 70 years around the world. In China about 450 million people live in iodine-deficient areas. The prevalence of endemic goitre in 7- to 14-year-old children was estimated to be 20% (7 million cases). The Chinese government has undertaken to eliminate iodine-deficiency disorders by the year 2000, and the manufacture and use of iodized salt throughout China has been compulsory since early 1995. Currently, potassium iodate is used. National regulations require the iodine content of iodized salt to be no less than 30 mg/kg in the salt-processing plant, no less than 25 mg/kg in the market, and no less than 20 mg/kg in the household. According to sporadic sample checking, however, the iodine content of salt in the market and the household is far from satisfactory. The loss of iodine during cooking is as high as 50% to 70%. The major problems in the fortification of salt with iodine in China are the use of uniodized salt in remote areas, an unsatisfactory system for monitoring the quality of iodized salt, the lack of knowledge and skill among marketing staffs, the loss of iodine during storage and cooking, and the lack of nationwide systematic studies to monitor the effectiveness of iodized salt in the control of endemic goitre.

Introduction

About 1,500 million people, or nearly one-third of the earth's population, live in areas of iodine deficiency. Its consequences, the iodine-deficiency disorders, include irreversible mental retardation, goitre, reproductive failure, increased child mortality, and socio-economic compromise. All of these results can be prevented by

sufficient iodine in the diet. Eliminating iodine deficiency is recognized as one of the most achievable of the goals that the 1990 World Summit for Children set for the year 2000.

Iodized salt is the best means to provide iodine to iodine-deficient populations. It is physiological, simple, practical, and effective. It has been used successfully and safely for over 70 years in programmes around the world. The Codex Alimentarius standard for food-grade salt permits the use of sodium and potassium salts of iodides and iodates in the iodization of salt. The level of fortification that has been used ranges from 30 to 200 ppm, which will provide enough iodine to meet the requirement of 150 to 200 µg per person per day [1]. In China, although iodized salt has been commercially available for more than 40 years, it was 1995 before its use became mandatory throughout the country.

Prevalence of iodine deficiency and iodine-deficiency disorders in China

About 450 million people live in iodine-deficient areas of China, and more than 30% of the total population is at risk for iodine-deficiency disorders. The average prevalence of endemic goitre in children between the ages of 7 and 14 was estimated to be 20% in 1995. All of mainland China's 30 provinces have reported the occurrence of iodine-deficiency disorders, primarily endemic goitre; however, there are significant differences in prevalence among geographic regions. There is at least a 40-fold difference between the county with the lowest prevalence and the county with the highest prevalence. It is estimated that in China in 1993 and 1994, there were more than 7 million cases of endemic goitre and more than 200,000 cases of cretinism [2].

It is widely acknowledged that most iodine-deficient areas are located in hilly or mountainous regions. However, it has been uncertain whether iodine deficiency is an issue of public health concern in large cities in China. A recent investigation demonstrated that subclinical iodine deficiency (urinary iodine < 100 µg/L) was quite

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common in schoolchildren in some large cities, such as Shanghai, Zhengzhou, Hefei, and Fuzhou (table 1) [3].

Government actions to control iodine-deficiency disorders

The Chinese government has undertaken to eliminate iodine-deficiency disorders by the year 2000. In 1994 the Ministry of Health and the Ministry of Light Industry jointly promulgated the programme outlines for accomplishing this. The strategic goals of this project are the following: all salt for human and animal use should be iodized; 95% of the population should use iodized salt; more than 95% of special populations (newly married women, pregnant women, lactating mothers, infants, and young children) should use iodine oil; and 95% of the counties should meet the criteria for elimination of iodine-deficiency disorders (prevalence of endemic goitre in schoolchildren < 5%).

To ensure the mandatory nationwide use of iodized salt, in August 1994 the State Council of the People's Republic of China promulgated the Regulation on Adding Iodine to Salt to Eliminate Health Hazards Due to Iodine Deficiency. It stipulated that the health administration department in the State Council shall be responsible for the control of health hazards caused by iodine deficiency and the health inspection and supervision of iodized salt, and that the salt administrative department in the State Council shall be responsible for the manufacture and marketing of iodized salt. According to the regulation, the mandatory manufacture, distribution, and use of iodized salt throughout China began on 1 October 1994 (Order No. 163 from the State Council of the People's Republic of China, 23 August 1994).

Effectiveness of use of iodized salt

Although the nationwide use of iodized salt was not started until early 1995, the effectiveness of iodized salt in the control of endemic goitre was clearly shown in several observations and trials. Table 2 shows the consistent reduction in the prevalence of goitre at the provincial, city, and county levels, where the use of iodized salt was mandatory in every household, although no parallel control population was available in those observations [4-11]. However, considering the large differences in climate, dietary patterns, cooking habits, and other lifestyle factors among various parts of China, the effectiveness of iodized salt in controlling iodine-deficiency disorders needs further studies and long-term monitoring.

TABLE 1. Urinary iodine concentrations in 10-year-old schoolchildren in 10 large Chinese cities

City	N	Median iodine concentration (µg/L)
Beijing	1,226	137.3
Shanghai	1,427	71.3
Wuhan	1,074	178
Jinan	1,175	100.3
Shenyang	1,153	109.8
Xian	1,196	178
Harbin	1,178	95.4
Zhengzhou	1,200	77
Hefei	1,190	75.4
Fuzhou	1,195	57

TABLE 2. Effects of iodized salt on the control of endemic goitre in 7- to 14-year-old children

Location	Duration of consumption	% reduction in goitre prevalence
<i>Provinces</i>		
Jiangxi	1982-92	21.0 ± 7.6
Shandong	1993-94	20.7 ± 11.3
<i>Cities</i>		
Jianou, Fujian	1984-92	47.0 ± 9.5
Shenyang, Lioing	1978-87	44.8 ± 7.1
<i>Counties</i>		
Shangzhi, Heilongjioang	1983-87	31.4 ± 4.3
Xide, Sichuan	1977-82	31.9 ± 2.5
Guangrao, Shandong	1987-91	15.0 ± 10.9

Manufacture and use of iodized salt

Different types of salt are used as the substrate for iodized salt, depending on the sources available in specific areas. The major types of salt in China include sea salt, lake salt (solar salt), and mined salt. There are 109 salt plants in China, with an annual production capacity of 800 million tons of iodized salt. According to the Ministry of Health, in 1995 the total production reached 639 million tons, of which 600 million tons were sold. Most plants adopted the spraying method for fortification of salt with iodine, which caused considerable loss of iodine because of the high temperature during spraying. However, the facilities in all 109 plants were renovated in 1996 with financial support from the World Bank and other agencies. Improvements in packaging technology were completed by the end of 1997.

Since 1990 potassium iodate (KIO₃) has replaced potassium iodide (KI) for iodization of salt in China.

National regulations require the iodine content of iodized salt to be no less than 30 mg/kg at the production level, no less than 25 mg/kg at the market level, and no less than 20 mg/kg at the household level. In order to reach these criteria, the actual level of fortification during salt processing must be 40 mg/kg.

Preliminary studies have shown, however, that the iodine content of iodized salt decreases continuously during the whole process from the salt plant to the consumer, depending on manufacturing methods, packaging materials, and storage time. The shortest half-life was found to be 12 weeks [12]. In general practice, the storage time is about one month in the plant and three months in the marketing system (provinces and counties). However, in some remote areas, the storage period could be as long as six months.

In order to examine the quality of the iodized salt supply, the Ministry of Health recently conducted a nationwide survey after one year of compulsory manufacture and use of iodized salt. The results showed that 80% of the salt used at the household level contained iodine, but only 51% of the samples met the requirement for iodine content (20 mg of iodine per kilogram of salt). At 20 of 22 national monitoring points for iodine-deficiency disorders where iodized salt has been used for a longer period, the salt samples did not meet the required iodine concentration [13]. A case study in Shandong province demonstrated that the iodine content of iodized salt decreased progressively from 75% in the fortification plant, to 49% in county warehouses, to 8% in the local market, and finally to 7.6% in the households [5]. This decrease indicates that in addition to iodine loss, other factors may account for the low levels of iodine found in the salt purchased by consumers, including low levels of iodine added during processing, the use of cheap, uniodized salt (especially in remote, poor areas), and the use of locally produced crude salt as a substrate.

Cooking loss is another major reason for the failure of control of iodine-deficiency disorders by iodized salt. Since recipes and cooking procedures vary in different parts of the country, and the number of dishes using salt is so large, it is difficult to know the overall iodine loss during cooking, and so far very little information is available. Preliminary unpublished data from the Institute of Nutrition and Food Hygiene of the Chinese Academy of Preventive Medicine show that the

loss of iodine during conventional Chinese cooking ranges from 50% to 70%.

At present the Chinese recommended daily intake of iodine is 150 to 200 mg per person per day, and the criteria for elimination of iodine-deficiency disorders in children aged 7 to 14 years are a prevalence of endemic goitre of less than 5% and urinary iodine content above 100 mg/L. According to the nationwide nutrition survey conducted in 1992, the mean daily intake of salt was 13.8 g per person, indicating that the daily intake of iodine should have been 276 mg per person based on the government fortification standard of 20 mg/kg. Taking all these factors into account, the dietary intake situation is far from satisfactory.

Major problems in iodine fortification

The Chinese government is determined to reach the goal of elimination of iodine-deficiency disorders by the year 2000 by using iodized salt as the major control measure in the general population. The national iodized salt programme has been implemented since early 1955, but there are major problems in enforcing it. These problems include the use of uniodized salt in remote rural areas combined with the lack of adequate processing technology in these areas, which results in iodized salt of poor quality that does not meet the national standard; an unsatisfactory system for monitoring the quality of iodized salt, which provides no guarantee that the salt used by consumers will meet the national standard; the lack of knowledge of the public health significance of iodine-deficiency disorders and the importance of iodized salt for its control among the marketing staffs of companies that process and sell salt; the loss of iodine during storage and cooking; and the absence of nationwide systematic studies on the effectiveness of iodized salt in controlling iodine-deficiency disorders (although its effectiveness in individual areas has been established). The appropriate concentration of iodine in salt for the Chinese population has not been established, given the characteristics of salt manufacturing, transportation, storage, and cooking. There is much to do to achieve the government's goal of eliminating iodine-deficiency disorders in China by the year 2000.

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Summary of panel discussions

Getting started on food fortification

Dr. Penelope Nestel, of Opportunities for Micronutrient Intervention (OMNI) in the United States, summarized the barriers to the process of developing a food fortification programme. Foremost among these is the issue of cost, which is often assumed to be high. However, it is estimated that the annual cost per person covered is less than US\$0.30 for vitamin A-fortified sugar, between US\$0.10 and US\$0.84 for iron-fortified sugar and salt, and US\$0.04 for iodized salt. The cost is often less than 2% of the retail cost of the product. Other barriers include poor motivation and commitment of both government and industry, concerns about the complexity of the technology, identifying a suitable vehicle, the legislation or regulations required, a quality assurance system, and sustainability. In starting a fortification programme, Dr. Nestel emphasized the need for developing a political will. This requires the provision of adequate information on the nutritional problem being addressed and an understanding of all the elements of a fortification programme.

Dr. Muhilal, Director of the Nutrition Research and Development Centre in Bogor, Indonesia, to illustrate the conduct of clinical and field trials to determine the effectiveness of food fortification, described his centre's experience with the fortification of monosodium glutamate (MSG) with vitamin A. After identifying vitamin A deficiency as a problem that could be solved by food fortification, a suitable vehicle, MSG, was identified on the basis of a national survey. After acceptance of the technology of fortification by industry, a clinical and field trial was conducted to determine whether the addition of vitamin A to MSG could reduce the level of xerophthalmia and raise serum vitamin A significantly. Sample size was estimated on the basis of the prevalence of xerophthalmia in the area covered. Data were collected at baseline and 6 and 11 months after the fortified MSG was marketed. Dr. Muhilal also described his centre's experience with the fortification of instant noodles with vitamin A and iron. The indicators used to evaluate success were the in-

crease in serum vitamin A and haemoglobin among children under five and pregnant women. Consumption of the fortified instant noodles was supervised by field workers three times a week for three months. Finally, Dr. Muhilal emphasized the important role of industry in getting fortification started. Although the development of technology starts at the research centre, that technology will eventually be transferred to industry. Therefore, advocacy to industrial managers is very important.

Dr. Kenny C. K. Koh, Area Technical Manager of Roche Singapore, discussed the importance of a quality assurance programme in food fortification. Food technologists and nutritionists need to know the extent to which the food processes and distribution systems can affect the retention of the added micronutrients and how they may minimize losses. They must not only know the technology of combining ingredients to produce attractive, safe, and nutritious foods, but also give serious consideration to labelling and cost implications. Dr. Koh emphasized the importance of an effective monitoring and surveillance system in the field together with an efficient quality control system at the manufacturing level. Inspection procedures should be risk-based, and quality assurance procedures should be based on Hazard Analysis and Critical Control Points. Finally, to ensure safe and acceptable food fortification, national guidelines must be developed following international guidelines such as the Codex Alimentarius.

Dr. Demetria C. Bongga, Nutrition Program Officer of UNICEF Philippines, discussed the data that are required before starting a fortification programme. These include the prevalence of micronutrient deficiency, which members of the population are affected, the causes of the deficiency, the recommended dietary allowance (RDA) of the nutrient, consumption data for potential vehicles, the availability of the micronutrient from the typical diet, the status of potential vehicles, the processing industry chain, the technology of fortification, and the existing guidelines for fortification, if available. After government and the private food sector have been convinced of the significant contribution that for-

tified foods can make in reducing micronutrient deficiency, a number of pilot production activities are needed. The food industry should be provided with assistance in the development or transfer of available fortification technology in the form of incentives such as procurement of equipment, training of plant personnel, and setting up of quality control systems. Research is important to determine the potency and stability of the fortificant, changes in physical and organoleptic qualities of the fortified product, and bio-availability of the fortificant. Standards of proper storage, appropriate packaging, and guaranteed shelf life for fortified foods should be developed. Finally, field trials should be conducted to determine efficacy and effectiveness at the same time as formative research on consumer acceptability. Dr. Bongga concluded that the success of food fortification relies heavily on the active participation of the private food industry with government, providing clear policies and guidelines as well as needed technical assistance.

Mrs. Asuncion L. Macalalag, Acting Executive Director of the National Nutrition Council in the Philippines, discussed the various roles that government should play in getting fortification started and encouraging multisectoral participation based on the Philippine experience.

First, the government's role is to provide a ripe environment for food fortification. In the case of the Philippines, three major policy instruments guided the start of food fortification: the Philippine Constitution, the Medium-Term Philippine Development Plan, and the Philippine Plan of Action for Nutrition. The latter, in particular, provided food fortification as one of the impact programmes under the plan. Official and unofficial pronouncements by the President of the Philippines and the Secretary of Health expressed support for food fortification. National nutrition surveys by the Food and Nutrition Research Institute supplied scientific information on the extent of micronutrient malnutrition.

Second, the government should initiate action and build momentum for food fortification through advocacy meetings and conferences among government agencies, local government units, non-governmental organizations, business leaders, and food manufacturers. In the Philippines the first advocacy meeting was led by the President himself. This was followed by others, including conferences to which foreign experts were invited to describe their experiences. In all of these advocacy meetings, the private sector figured prominently among the participants. At the same time, technology development and research on the various aspects of food fortification were intensified.

Third, the government maintains the momentum through catalysing and enabling actions to hasten the adoption and implementation of food fortification. In the case of the Philippines, the catalysing and enabling

role of government took the form of initially creating the demand for fortified food through public information campaigns, training of producers and traders, soft loans for the acquisition of equipment, passage of the Salt Iodization bill, and instituting the Sangkap Pinoy seal programme through which food manufacturers meeting the requirements for fortification were awarded a seal of approval by the Department of Health. The seal was licensed to be printed on the labels of the fortified food product.

Aside from its advocacy role as the initiator, catalyst, and enabler, government plays coordinative and integrative functions. In the Philippines this function resides with the National Nutrition Council, the highest policy-making and coordinating body for nutrition in the country. To address the problem of micronutrient malnutrition more efficiently, the National Nutrition Council organized the National Micronutrient Action Team, the members of which come from governmental and non-governmental agencies and academic institutions. In addition, the Food Fortification Interagency Committee was formed under the National Micronutrient Action Team, calling for private-sector representatives when needed. Finally, the last role that government should assume is that of a regulator. In assuming this role, the Philippine government has established guidelines for the fortification of foods and is now instituting quality assurance systems to ensure the quality of fortified products in the market.

In assuming all these roles, a major challenge for government is to bring about multisectoral participation. This involves food manufacturers, providers of fortificants, sources of technologies, and those who can promote the consumption of fortified foods, including mass media and consumer organizations.

Educational advocacy, policy, and legislation

Mrs. Adelisa C. Ramos, Director of the Nutrition Service of the Department of Health, Philippines, focused on social marketing and advocacy as indispensable ingredients for success in food fortification. Using Philippine experience, particularly with salt iodization, she cited various strategies for social marketing, consisting of communication campaigns, lobbying with legislators, salt industry research, community organization, networking with industry and other sectors, and creation of an organizational structure for programme implementation. The primary targets of the social marketing strategy for iodized salt were mothers. The secondary targets were legislators, local government executives, and health workers. The implementation process of social marketing started with formative research that provided the basis for the campaign, followed by the preparation of a communication plan,

the conduct of a Quick Response Survey to determine the strengths and weaknesses of the plan, and finally the implementation of the plan. In fact, a second Communication Plan was implemented on the basis of the results of the first Quick Response Survey. The second Communication Plan resulted in increases in the level of awareness of iodized salt from 66% to 79% and in the level of utilization from 15% to 37% in the areas covered.

Mrs. Ramos also discussed how the Philippines worked for the passage of the Salt Iodization Law, which was passed by Congress and signed by the President in 1996. To sustain the programme, she emphasized the need to promote continued collaboration between the public and private sectors, conduct advocacy meetings, intensify the tri-media campaign, continue education for the programme advocates, provide logistic and technical support to small salt producers, and periodically evaluate the impact of advocacy and social marketing efforts.

Ms. Zahara Merican, of the Malaysian Agricultural Research and Development Institute, cited the case of food fortification in Malaysia. The current Malaysian food regulations address two concerns: mandatory fortification of particular foods, such as fortification of condensed milk and margarine with vitamin A and fortification of iodine with salt in the state of Sarawak; and voluntary fortification of various foods, from bread to snacks and drinks. The current thinking in Malaysia is to continue to encourage voluntary fortification. Only when advocacy and persuasion fail will regulations be used to address nutritional requirements.

Prof. Pakdee Pothisiri, Secretary General of the Food and Drug Administration in Thailand, emphasized that food-fortification programmes need to be supported by suitable legislation and regulations. The primary purposes of food legislation are to protect the health of the consumer and to protect the consumer from fraud. Procedures for monitoring the premises where fortified foods are prepared, packed, stored, or held for sale, as well as for penalizing defaulters, must be clearly defined. Standards for fortified foods and labelling requirements must also be contained within food regulations. In the light of the Agreement on Technical Barriers to Trade, the development of international standards for fortified foods is an important step in the elimination of technical barriers. Professor Pothisiri further emphasized that food laws are best managed in two parts: the basic food act itself, which sets broad principles, and food regulations, which contain the detailed provisions concerning the different categories of products. This will allow flexibility in the face of new scientific knowledge and technologies.

Dr. Leila G. Saldanha, Nutrition Asia-Pacific Director, Kellogg (Australia), pointed out the need to examine food fortification at three levels in the light of rapid advances in knowledge about nutrients and their role in health promotion and disease prevention. The

levels are fortification to treat or prevent nutrient-deficiency diseases, fortification for better nutrition (i.e., fortification of foods to allow achievement of nutritional goals without dramatic dietary changes), and fortification to promote optimum health, which involves levels and combination of nutrients to prevent diseases associated with affluence, such as heart disease, cancer, and cataracts. Finally, Dr. Saldanha underscored the important role of industry in developing technologies to deliver key nutrients to the population. Through innovative partnerships among government, professional groups, private agencies, and the food industry, new technologies can be made available, communication programmes can be developed, and an acceptable regulatory environment can be established.

Monitoring and evaluation

Dr. Oscar Pineda, of the Latin American Centre for Nutrition and Metabolic Studies (CELANEM), discussed the elements that make up a workable monitoring and evaluation system. Monitoring is done at three levels. First, at the site where premixes are prepared, a daily or lot analysis has to be performed in order to ensure the quality of the premix. At this point, a 5% variation may be expected. Second, at the fortification site, periodic daily quick analyses are required to maintain correct levels of fortification. A larger variation of 15% to 20% is usually found at this stage. Third, at the population consumption level, monitoring should be the responsibility of local health authorities, and an organization should be set up to allow for quick analysis of samples and rapid feedback of results.

Evaluation involves determining the impact on and the level of consumption of the fortified food by the population. In general, an evaluation interval of six months is adequate, as shown by the experience with vitamin A-fortified sugar. In the case of milk and flours fortified with iron bis-glycine chelate, a highly significant effect can be measured in two to three months.

Except at the population level, the organization required for monitoring is essentially that of industry. On the other hand, for evaluation, the organization and facilities of the public health sector are essential to carry out periodic surveys of the impact on representative samples of the population.

Dr. Martin Bloem, Country Director of Helen Keller International in Jakarta, observed that in the last few years there has been a growing emphasis on fortifying foods with vitamin A and improving the diet of the population at risk following the success of vitamin A supplementation programmes in reducing vitamin A deficiency. He cited the cases of Bangladesh, Vietnam, the Philippines, and Indonesia, where distribution of vitamin A capsules has been successful. The problem is the need for guidelines for phasing out the vitamin

A capsule programme and going into fortification and dietary diversification. Dr. Bloem proposed a model for determining whether to phase out vitamin A capsule distribution based on a biomedically sound scientific framework. By doing an effectiveness study on the vitamin A capsule distribution programme, the government can decide whether it needs to continue the programme or go to food fortification and dietary diversification. Monitoring the effectiveness of food fortification can then follow the system for monitoring vitamin A capsule distribution.

Ms. Carmina J. Parce, of the Bureau of Food and Drugs in the Philippines, using the experience with salt iodization in the Philippines, discussed the framework for monitoring universal salt-iodization programmes. The essential elements of internal quality assurance by the producer include purchase of quality raw materials and supplies, validation of the production process, routine inspection of equipment, monitoring of iodine levels in the final product before distribution, and documentation of monitoring protocols and results. External quality assurance is carried out by food regulatory agencies and consists of monitoring products and processes for compliance with requirements for product standards and good manufacturing practices. During inspections, it is essential to verify that the producer is performing internal quality assurance, that records are being maintained, and that appropriate corrective measures are being taken. In addition to monitoring the quality of iodized salt produced in the country, it is essential, at least in the Philippines, where large volumes of salt are imported, that imported salt is also monitored to determine its contribution towards meeting the national iodized salt requirements.

The effectiveness of the salt-iodization programme

can be assessed by monitoring at the household level. In the Philippines a community-based salt-monitoring strategy using the school system has been designed to gather data on household levels of consumption of iodized salt. Finally, Ms. Parce described the monitoring system for the Sangkap Pinoy seal programme in the Philippines, which is intended to encourage voluntary fortification of foods with vitamin A, iron, and iodine by food manufacturers. A technical board first determines whether the criteria to qualify for the seal are satisfied by the manufacturer. After the seal has been granted, monitoring activities consist of periodic assessment of the company's quality management system, evaluation of monitoring data on claimed fortificant levels, and review of promotion materials. A network of government and private laboratories has been identified by the Bureau of Food and Drugs to provide analytical services.

Mr. Ricardo M. Dizon, Quality Control Section Manager of the Philippine Dairy Products Corporation, described the monitoring and evaluation system that his company employs in fortifying margarine with vitamin A. To fully satisfy the criteria for a successful food-fortification programme, the following must be taken into consideration: vitamin A potency and safety as per label and copy claims (the predetermined level of vitamin A should be maintained, with consideration given to expected shelf life, and the right kind and amount of antioxidants should be used); affordability and accessibility of the product through a reasonable price and an aggressive marketing network; strict quality control measures at the plant; and monitoring of vitamin A activity in trade samples (quarterly monitoring in supermarkets and retail stores, including those in far-flung areas, is recommended).

International Life Sciences Institute Regional Conference on Food Fortification: Science, Technology, and Policy 3–5 December 1996 Manila Declaration on Food Fortification

We, the participants of the Regional Conference on Food Fortification,

Recognizing that:

- » Micronutrient malnutrition, especially of iodine, vitamin A, and iron, is highly prevalent in much of Asia;
- » Micronutrient malnutrition is incompatible with the good health and well-being of all individuals, especially women and young children, and with the social and economic development of nations;
- » Micronutrient malnutrition adversely affects learning and productivity of the individual and consequently the social and economic activity of nations;
- » The control of these micronutrient deficiencies through food fortification offers an opportunity to improve the quality of lives at low cost in a reasonable time period;
- » For food fortification to succeed, appropriate policies and various scientific, technological, economic, and logistic issues need to be addressed;

Hereby declare that:

- » The continued high prevalence of micronutrient malnutrition in any country is unacceptable, and every country's efforts towards its elimination should be supported;
- » It is imperative that academic, government, private, and non-governmental organizations lend expertise and share resources to develop and apply responsible and appropriate food-fortification programmes to eliminate nutritional deficiencies;
- » We will work together to open channels to collaborate in policy development and in the application of technology and research for fortification programmes to succeed;
- » Since the success of a food-fortification programme

relies on the acceptance of the programme by the general public, we will collectively work towards promoting public awareness and acceptance through responsible communication.

In support of the declaration:

- » We urge national governments to lead the efforts to eliminate micronutrient deficiencies in their respective countries, commencing with the timely identification of population needs and appropriate solutions that may include food fortification suitable for local conditions;
 - » We urge national governments to adopt Codex Alimentarius standards for food fortification to harmonize international efforts and ensure safe and effective food fortification;
 - » We urge governments of countries with populations at high risk of nutritional deficiencies to regulate the fortification of appropriate foods;
 - » We request national governments, together with the food industry, to build the infrastructure in support of food-fortification efforts and to adopt strict quality control standards and monitor closely the process and outcome;
 - » We urge national governments to provide incentives and assistance to the food industry to ensure the timely implementation of effective food fortification at an affordable cost;
 - » We urge all sectors, including the food industry as well as academic, international, and bilateral organizations, to forge partnerships with national governments to implement successful food fortification.
- Participants of this conference come from the government, major food industries, academia, and non-governmental sectors throughout the regions of the world.

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3–5 December 1996

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Books received

The international code of marketing of breast-milk substitutes. A common review and evaluation framework. Nutrition Unit, Division of Food and Nutrition, World Health Organization, Geneva, 1996. 134 pages, paperback.

The development of the International Code of Marketing of Breast-Milk Substitutes at a landmark 1979 WHO/UNICEF meeting and its adoption in 1981 by nearly all member countries of WHO has contributed importantly to protecting and improving breastfeeding practices worldwide. Nevertheless, there is continuing controversy over the degree of compliance with its provisions and indeed with their interpretation. This volume provides guidelines for in-depth review and evaluation of the status of the application of the code in a country. The original guidelines used in 14 WHO member states have been revised and refined after further field testing in two more countries.

Introduction to clinical nutrition. Vishwanath M. Sardesai. Marcel Dekker, New York, 1998. (ISBN 0-8247-9865-1) 481 pages, hardcover. US\$75.00.

This volume is designed for teaching nutrition to medical students during their preclinical years. It is designed to follow a course in biochemistry. Part I covers biology and biochemistry, including the fundamentals of

nutrition, digestion, requirements for energy, carbohydrates, fat and protein, role of essential fatty acids, eicosanoids, minerals, vitamins, and vitamin-like substances. Part II covers the special nutritional needs during pregnancy, lactation, and the life cycle. Part III deals with the assessment of nutritional status and the interaction of nutrition and specific diseases, including obesity, hyperlipidaemias, osteoporosis, diabetes, and genetic diseases. Part IV includes special topics, such as dietary fibre, antioxidants, vegetarianism, food additives, and the metabolism of toxic substances in foods. The book is intended for students who are directing their careers towards community medicine and family practice and covers clinical nutrition of the individual well. Chapters on nutritional epidemiology at the family and population level would have been desirable.

Nonthermal preservation of foods. Gustavo V. Barbosa-Canovas, Usha R. Pothakamury, Enrique Palou, and Barry G. Swanson. Marcel Dekker, New York, 1998. (ISBN 0-8247-9979-8) 276 pages, hardcover. US\$135.00.

This book summarizes information otherwise available only in journal articles on individual topics. Replacing or complementing thermal processes for improving the quality of the food supply and reducing costs has great potential.

Note for contributors

The editors of the *Food and Nutrition Bulletin* welcome contributions of relevance to its concerns (see the statement of editorial policy on the inside of the front cover). Submission of an article does not guarantee publication—which depends on the judgement of the editors and reviewers as to its relevance and quality. All potentially acceptable manuscripts are peer-reviewed. Contributors should examine recent issues of the *Bulletin* for content and style.

Language. Contributions may be in English, French, or Spanish. If French or Spanish is used, the author should submit an abstract in English if possible.

Format. Manuscripts should be typed or printed on a word processor, **double-spaced**, and with ample margins. Only an original typed copy or a photocopy of equivalent quality should be submitted; photocopies on thin or shiny paper are not acceptable.

When the manuscript has been prepared on a word processor, a diskette, either 3½- or 5¼-inch, should be included with the manuscript, with an indication of the disk format and the word-processing program used.

Length. Ordinarily contributions should not exceed 4,000 words.

Abstract. An abstract of not more than 150 words should be included with the manuscript, stating the purposes of the study or investigation, basic procedures (study subjects or experimental animals and observational and analytical methods), main findings (give specific data and their statistical significance if possible), and the principal conclusions. Emphasize new and important aspects of the study or observations. Do *not* include any information that is not given in the body of the article. Do not cite references or use abbreviations or acronyms in the abstract.

Tables and Figures. Tables and figures should be on separate pages. Tables should be typed or printed out double-spaced. Submit only original figures, original line drawings in India ink, or glossy photographs. Labels on the figures should be typed or professionally lettered or printed, not handwritten.

Photographs. Ideally photographic materials should be submitted in the form of black and white negatives or black and white glossy prints. Photographs will not be returned unless a specific request is made.

Units of measurement. Preferably all measurements should be expressed in metric units. If other units are used, their metric equivalents should be indicated.

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